

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

<b>IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION</b>	)	<b>MDL No. 1456</b>
	)	<b>Master File No. 01-12257-PBS</b>
	)	<b>Subcategory Case No. 06-11337</b>
	)	
<b>THIS DOCUMENT RELATES TO:</b>	)	<b>Judge Patti B. Saris</b>
<i>State of California, ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., et al.</i>	)	<b>Magistrate Judge</b>
Case No: 1:03-cv-11226-PBS	)	<b>Marianne B. Bowler</b>
	)	
	)	

**PLAINTIFFS' RESPONSE TO DEFENDANTS' JOINT LOCAL RULE 56.1  
STATEMENT OF UNDISPUTED MATERIALS FACTS IN SUPPORT OF THEIR  
MOTIONS FOR PARTIAL SUMMARY JUDGMENT AND STATEMENT  
OF ADDITIONAL UNDISPUTED FACTS IN OPPOSITION TO  
DEFENDANTS' MOTIONS FOR PARTIAL SUMMARY JUDGMENT**

Pursuant to Rule 56.1 of the Local Rules of this Court, Plaintiffs hereby submit their Response to Defendants' Statement of Undisputed Material Facts in Support of Defendants' Motion for Partial Summary Judgment and Statement of Additional Undisputed Facts in Opposition to Defendants' Motions for Partial Summary Judgment. In the responses that follow, any statement submitted by Defendants that Plaintiffs do not dispute is undisputed solely for purposes of Plaintiffs' response to Defendants' motions for partial summary judgment. Plaintiffs reserve the right to dispute any such statement of fact for purposes of trial. *See LR 56.1.*

**I. THE MEDICAID PROGRAM**

1. The Medicaid program was signed into law in 1965 as part of Title XIX of the Social Security Act and is a joint federal-state program that provides medical assistance to financially needy patients. *See 42 U.S.C.A. § 1396-1 (2009).*

Plaintiffs' Response: Plaintiffs do not dispute the statement, but clarify that Medicaid is a federal-state program to assist the poor, elderly, and disabled in obtaining medical care, and does not provide medical services itself. 42 C.F.R. § 430.0 (2009). Under the Medicaid Act, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396 -1396v, the federal government provides

financial support to states that establish and administer state Medicaid programs in accordance with federal law through a state plan approved by HHS. 42 U.S.C. § 1396; 42 C.F.R. §§ 430.0, 430.10 - 430.20 (2009).

2. The Medicaid program is jointly funded by states and the federal government. The federal government pays for a share of each state's Medicaid program expenditures which ranges from 50% to 83%. *See* 42 U.S.C.A. § 1396d(b) (2009).

Plaintiffs' Response: Undisputed.

3. In 1987, CMS, then known as the Health Care Financing Administration ("HCFA"), after a Task Force report and recommendation, adopted regulations governing reimbursement payments for healthcare services provided by state Medicaid programs, including payments for drugs. *See* 42 C.F.R §§ 447.301 to 447.333. Those regulations remained in effect and did not substantially change from January 1, 1994 to December 31, 2004 (the "Relevant Time Period").

Plaintiffs' Response: Plaintiffs do not dispute that HCFA enacted the regulations cited above in 1987, but note that the notice of final rulemaking only references concerns expressed to a task force and does not reference either a task force report or recommendation. 52 Fed. Reg. 28648 (July 31, 1987). Plaintiffs do not dispute the last sentence in the preceding SOF.

4. CMS provides individual states substantial discretion in designing their Medicaid programs. *See* 42 C.F.R § 447.502 (2009); 42 C.F.R § 447.302 (2009); 42 C.F.R § 447.304 (2009); 42 C.F.R § 447.512 (2009); 42 C.F.R § 447.514 (2009); 42 C.F.R § 447.518 (2009).

Plaintiffs' Response: Plaintiffs object to Defendants' attempt to cast a purported statement of policy interpretation as a fact, and their attempt to use LR 56.1 as a vehicle to describe their view of the law or to obtain admissions by the Plaintiffs on matters of law.

5. State Medicaid agencies must act in accordance with their State Plan, which CMS reviews and approves annually. *See* 42 C.F.R § 447.201 (2009); *see* 42 C.F.R § 447.518 (2009).

Plaintiffs' Response: Plaintiffs object to Defendants' attempt to use LR 56.1 as a vehicle to describe their view of the law or to obtain admissions by Plaintiffs on matters of law. Further, the regulations cited by Defendants do not reference annual review and approval of state plans.

Finally, to the extent Defendants suggest they have any standing to complain about a possible discrepancy between California's actual reimbursement practice and California's State Plan, Defendants are wrong. *Long Term Care Pharmacy Alliance v. Ferguson*, 362 F.3d 50 (1st Cir. 2004).

6. However, within the broad federal requirements set by CMS, states have considerable flexibility in designing their State Plans. (Robben Decl., Ex. 2 at 431:4-9; Robben Decl., Ex. 3 at HHC002-0565.)

Plaintiffs' Response: Plaintiffs do not dispute that a CMS official testified that states had "flexibility" in "designing their systems." However, Plaintiffs dispute the materiality of this paragraph. Further, the excerpts quoted from the letter constitute inadmissible opinion evidence regarding the purpose or effect of a statute. *See, e.g., Thornburg v. Gingles*, 478 U.S. 30, 43 n. 7 (1986) ("We have repeatedly recognized that the authoritative source for legislative intent lies in the Committee Report..."). Plaintiffs additionally dispute this paragraph to the extent it asserts or implies that California had the "flexibility" to establish or implement payment amounts that were not permitted by federal law. California had no authority to implement payment amounts for the drugs at issue in this litigation exceeding the Estimated Acquisition Costs for those drugs, as that term is defined in federal and state statutes and regulations. Testimony by Medi-Cal and CMS officials establishes that although states had "flexibility" in administering their programs, that flexibility was constrained by federal regulations, including the estimated acquisition cost requirement. Medi-Cal officials testified that the California program understood and implemented the federal estimated acquisition cost requirement. (*See, e.g.*, Paul Decl. Ex. 1 (12/3/08 Rule 30(b)(6) CA Dept. of Health Care Servs. (Gorospe) Dep.) at 201:4-202:9.)

Plaintiffs also refer the Court to the United States' Common Statement of Facts (docket no. 6316, ¶¶ 29-34).

7. Bruce Vladeck, Administrator of CMS from 1993 to 1997, testified that states had leeway to be able to determine the specific ingredient reimbursement basis that they wanted, as long as it was acceptable to the federal government, and the federal government approved a variety of reimbursement methods that were consistent to federal law. (Robben Decl., Ex. 4 at 433:8-449:12.)

Plaintiffs' Response: Undisputed.

8. Mr. Vladeck testified as follows:

A. HCFA approved state plans that paid on some basis relative to AWP, because that's what the statute provided for.

Q. And in doing that you were approving plans that had the spread built into the reimbursement methodology. Right?

MS. BROOKER: Objection. Form.

A. Again, I would say that had a spread built into the reimbursement methodology.

Q. Fine. But you also had one state, at least, that had no spread. Right?

MS. BROOKER: Objection. Form.

MR. BREEN: Objection. Form.

A. Yes, that's correct.

(Robben Decl., Ex. 4 at 448:21-449:12.)

Plaintiffs' Response: Plaintiffs do not dispute that Mr. Vladeck testified as set forth above, but note that Mr. Vladeck also testified that he was not competent to testify as to the size of the spread. (Robben Decl. Ex. 4 at 447:10-14.)

9. Thomas Scully, Administrator of CMS from 2001 to January 2004, testified that it was CMS's policy to let the states make their own determination of what levels to reimburse providers at, and that it was up to the states' discretion whether they decided to reimburse at, for example, AWP minus 10% when CMS and the state knew that average actual acquisition cost was more like AWP minus 40%. (Robben Decl., Ex. 5 at 209:11-210:15.)

Plaintiffs' Response: Disputed. Plaintiffs do not dispute that Defendants accurately, but selectively, quote excerpts from Mr. Scully's testimony. The quoted testimony, however, is incomplete, misleading and does not support SOF 9. Deidre Duzor, Director of the Pharmacy Division for Medicaid, testified that CMS recognized states' difficulties in estimating acquisition costs, and that CMS approved state plans if it believed that the state was moving in the "right direction."

Q. But based on your experience you did observe that it was difficult to get states to establish payment rates in adherence with the estimated acquisition cost, correct?

MR. BATES: Objection to the form.

MS. MARTINEZ: Objection to form.

A. Well, in order to determine estimated acquisition cost my understanding of what had been done previously was to require states to do surveys and get invoices. And I think states were saying that that was too difficult, too time consuming, too out of date. By the time they did it prices were changing. So that states were telling us that they couldn't really do that anymore.

Q. Is it your testimony that you didn't know that states were reimbursing drugs at levels higher than estimated acquisition cost?

MR. WINGET-HERNANDEZ: Objection to form.

MR. BATES: Objection to form.

MS. MARTINEZ: Objection to form.

A. I think based on the IG reports, yes, we expected that they were. But they were faced with difficult choices in terms of reducing their payments, which many states were doing, but they were doing it in a cautious manner. They didn't want to do it in a very precipitous manner because of course their pharmacy – their pharmacist and their pharmacy organizations were telling people that the sky would be falling in then. So I think they were in a difficult position to know how much they could reduce their rates.

Q. Do you believe that their actions were reasonable?

MS. MARTINEZ: Objection to form.

MR. BATES: Objection to form.

A. I think we thought the direction they were going was the proper direction. Whether they were being overly cautious or not I think is a hard judgment at the federal level to make. But, you know, I think we thought they were going in the right direction.

(Paul Decl. Ex. 2 (10/30/2007 Deidre Duzor Dep.) at 195:6-197:3.)

Q. In order for you to approve this state plan would Minnesota need to provide you documentation that AWP minus 11 percent was their best estimate of the price that providers were currently and generally paying for drug products in Minnesota?

MS. MARTINEZ: Objection, form.

A. At the time our interest was encouraging states to reduce their payment. And so if they were going to be reducing their payment, as long as that would not result in an access problem we were generally accepting their documentation that this was a better payment than what would otherwise be paid, more appropriate payment.

Q. So this would fall under the decision memo options that we saw earlier in Abbott Exhibits 328 and 487?

MS. MARTINEZ: Objection, form.

A. I don't know that it would -- I wouldn't say it would fall under those. That was guidance or an expansion of the kinds of factors that we would look at as we were evaluating state plan amendments. So it is consistent with it to the extent that the result of this amendment would be to lower reimbursement to a more appropriate level than would otherwise be the case.

Q. What if the proposed amendment did not reduce the reimbursement amount to the prices at which pharmacies were generally and currently paying for drugs?

A. We did not have independent evidence as to what the pharmacies were currently paying for drugs. So, you know, we didn't have that information in order to compare to it. The only thing we had was the Inspector General's report.

(Paul Decl. Ex. 3 (2/27/08 Deidre Duzor Dep.) at 347:12-349:4.)

**“In the Aggregate”**

10. For multiple source drugs subject to an upper limit established by HCFA, the 1987 regulations limited payment in the aggregate, across all drugs, to the amount that would result from the application of the specific limits established by HCFA plus a reasonable dispensing fee. (Robben Decl., Ex. 6.)

Plaintiffs’ Response: Plaintiffs dispute Defendants’ characterization of the 1987 regulations. The language of the regulation (at 52 Fed. Reg. 28648, 28657 (July 31, 1987)) controls, not Defendants’ characterization. Further, it is inappropriate for Defendants to use LR 56.1 to advance their view of the law.

11. For all “other drugs” not subject to a Federal Upper Limit (“FUL”), a state agency’s payment “must not exceed, in the aggregate, payment levels that the agency has determined by applying the lower of the (1) EAC plus reasonable dispensing fees established by the agency; or (2) Providers’ usual and customary charges to the general public.” *See* 42 C.F.R. § 447.512(b) (2009).

Plaintiffs’ Response: Plaintiffs dispute Defendants’ characterization of the 1987 regulations. The language of the regulation (at 52 Fed. Reg. 28648, 28657 (July 31, 1987)) controls, not Defendants’ characterization. Further, it is inappropriate for Defendants to use LR 56.1 to advance their view of the law.

12. The regulations define “estimated acquisition cost” to be a state agency’s “best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers.” *See* 42 C.F.R. § 447.502 (2009).

Plaintiffs’ Response: Plaintiffs do not dispute the accuracy of the quoted language.

### **Access to Care**

13. A state agency’s reimbursement methodologies are subject to an access constraint: “The agency’s payments must be sufficient to enlist enough providers so that services under the plan are available to recipients at least to the extent that those services are available to the general population.” *See* 42 C.F.R. § 447.204 (2009).

Plaintiffs’ Response: Plaintiffs dispute SOF 13 because the regulation references actual “payments” to providers, not reimbursement methodologies.

14. Accordingly, state Medicaid agency personnel attempt to balance at least two competing goals when making policy decisions to set reimbursement rates: 1) achieve sufficient access to quality health care for the enrollees and 2) administer the program within the budget constraints imposed by the state legislature. (*See* Joint SOF *infra* at ¶¶ 52, 56, 57; *see also* Robben Decl., Ex. 7 at 108:3-109:13; Robben Decl., Ex. 8 at 307:13-308:5; Robben Decl., Ex. 9 at 464:2-465:7; Robben Decl., Ex. 10 at 49:10-51:18.)

Plaintiffs’ Response: Plaintiffs dispute SOF 14 because the testimony from state Medicaid employees from the various states selected by Defendants does not support the characterization of these goals as necessarily “competing.”

## II. THE MEDI-CAL PROGRAM

15. California's Medicaid program is known as Medi-Cal. (Robben Decl., Ex. 11 at 184:2-9.) It is administered by the California Department of Health Care Services, formerly known as the California Department of Health Services. *Id.* (Hereinafter, the California Department of Health Care Services, formerly known as the California Department of Health Services, shall be referred to as "DHS").

Plaintiffs' Response: Undisputed.<sup>1</sup>

16. Throughout the relevant time period, the Medi-Cal program has provided coverage for prescription drugs. (Robben Decl., Ex. 1 at ¶ 26.)

Plaintiffs' Response: Undisputed.

17. Single-source, or brand name, drugs account for approximately 80% of the Medi-Cal program's expenditures for drugs. Multi-source, or generic, drugs account for only approximately 20% of the Medi-Cal program's total expenditures for drugs. (Robben Decl., Ex. 11 at 192:14-193:12.)

Plaintiffs' Response: Undisputed.

18. Throughout the relevant time period, Medi-Cal reimbursed pharmacists and other Medicaid providers who dispensed the Subject Drugs at the lower of Estimated Acquisition Cost ("EAC"), the Federal Upper Limit ("FUL"), the Maximum Allowable Ingredient Cost ("MAIC"), or the charge submitted by the provider. (Robben Decl., Ex. 13.)

Plaintiffs' Response: Plaintiffs dispute SOF 18, as inaccurately stated. Throughout the relevant time period, Medi-Cal reimbursed pharmacists and other Medicaid providers who dispensed the Subject Drugs at the Estimated Acquisition Cost ("EAC"), which was the lowest of: AWP minus a statutorily defined percentage (minus 5%, minus 10%, or minus 17%), the Federal Upper Limit ("FUL"), the Maximum Allowable Ingredient Cost ("MAIC"), Direct Price (until 2002), the Selling Price (after September 2004), or the charge submitted by the provider. (Robben Decl. Ex. 13 (Pl.'s Resp. to Defs. Interrog. 13).)

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<sup>1</sup> Plaintiffs note that the relevant period alleged in Plaintiffs' case runs from January 1, 1994 through December 31, 2004. Throughout that period, the Medi-Cal program ("Medi-Cal") was administered by the California Department of Health Services ("DHS"). Effective July 1, 2007, the California Department of Health Services was renamed the California Department of Health Care Services ("DHCS"), which continues to administer Medi-Cal. DHS and DHCS are herein used interchangeably, but refer to the same entity.

19. From January 1, 1994 to November 30, 2002, EAC was defined in regulations as Average Wholesale Price (“AWP”) minus five percent. From December 1, 2002 to August 31, 2004, EAC was defined in regulations as AWP minus ten percent. From September 1, 2004 to the present, EAC has been defined as AWP minus 17 percent. (Robben Decl., Ex. 13.)

Plaintiffs’ Response: Plaintiffs dispute this SOF, as inaccurately stated. EAC was not so defined. (*See* Pls. Resp. to SOF 18.) From January 1, 1994 to November 30, 2002, the statutorily defined discount off of AWP which was used to set AWP-based reimbursement within California’s “lowest of” estimated acquisition cost methodology was defined in regulations as Average Wholesale Price (“AWP”) minus five percent. From December 1, 2002 to August 31, 2004, it was defined as AWP minus ten percent. From September 1, 2004 to the present, it was defined as AWP minus 17 percent. (Robben Decl. Ex. 13 (Pl.’s Resp. to Defs. Interrog. 13).)

20. Throughout the relevant time period, California has defined “AWP” as “the price for a drug product listed for a standard package in the Department’s primary price reference source.” See 22 CCR § 51513.

Plaintiffs’ Response: Disputed. California has not “defined” “AWP” as Defendants claim in SOF 20. Rather, the applicable statute explains that the term “Average wholesale price” refers to the price for a drug product listed in the department’s primary price reference source, which is, specifically, a price reported by Defendants to the department’s primary reference source (FDB) on each of their drugs. California’s reimbursement statute states that reimbursement is conducted under an estimated acquisition cost (EAC) “lowest of” methodology, that “AWP” is a component of EAC, and is therefore intended to be a price which represents “the department’s best estimate of the price generally and currently paid by providers for a drug product sold by a particular manufacturer or principal labeler in a standard package.”

*See CAL. WELF. & INST. CODE § 14105.45.*

21. From January 1, 1994 to August 31, 2004, California paid a dispensing fee of \$4.05. (Robben Decl., Ex. 13.) From September 1, 2004 to the present, California has paid a dispensing fee of \$7.25 (\$8.00 for drugs administered by long-term care facilities.) *Id.*

Plaintiffs' Response: Undisputed.

**III. CALIFORNIA'S UNDERSTANDING OF AWP AND REIMBURSEMENT METHODOLOGIES DURING THE RELEVANT TIME PERIOD**

22. Through both independent and government-sponsored studies, California has understood since well before the relevant time period that published AWPs, particularly those for generic drugs, did not reflect providers' actual discounted acquisition costs for drugs. (*See* Joint SOF *infra* at ¶¶ 23-40.)

Plaintiffs' Response: Disputed. Plaintiffs object to Defendants' heading and statements of fact to the extent that Defendants have "cherry-picked" isolated items from a complex historical record. Plaintiffs further object to any and all statements of fact to the extent that they relate to California's understanding "well before the relevant time period" as irrelevant and immaterial to the issues before the Court. At all relevant times (i.e., 1994 through 2004), California's reimbursement methodology was governed by CAL. WELF. & INST. CODE § 14105.45 and its implementing regulations, or predecessor regulation. *See* CAL. CODE REGS. tit. 22, § 51513. It is remarkable that while Defendants discuss at length facts purporting to show California's understanding "well before the relevant time period," they ignore the language and regulatory record of Section 51513, which governed during most of the relevant time period. (*See* *infra*, Plaintiffs' Statement of Additional Undisputed Facts ("CA SOAF Defs.") ¶¶ 18-19.) Any understanding that California officials may have had prior to 1989 is irrelevant and immaterial, given the fact that the Section 51513 and the subsequent statutes governing the reimbursement methodology and rate must be construed in accordance with their language and contemporaneous regulatory or statutory history. Plaintiffs further respond that California has understood at all relevant times that published AWPs did not reflect "actual discounted acquisition costs," but rather were intended to be an average of the wholesale prices for Defendants' pharmaceutical products that could reasonably be used in determining providers' estimated acquisition costs for those products. (*See* Pls.' Resp. to SOF 20.)

Finally, Defendants never came to California to explain the differences between their reported AWPs and actual provider acquisition costs for their drugs. (See CA SOAF Defs. ¶ 29.)

23. In 1977, the California Department of Finance issued a report entitled “Medi-Cal Drug Price Controls, A Staff Reference Report” (the “1977 Report”). (Robben Decl., Ex. 14.) The 1977 Report examined various possible cost-control measures for Medi-Cal’s prescription drug benefit. The 1977 Report documented that pharmacies could purchase drugs at significant discounts below AWP from manufacturers:

Manufacturers’ list prices to wholesalers and retailers, based upon inspection of the Red Book, appear to range from 14 percent below AWP from some manufacturers to 22 percent for others.

Average Wholesale Price less these published discounts is the maximum price the pharmacist can expect to pay if he buys direct from the manufacturer. The range of discounts below AWP is in fact very wide and apt to change rapidly. Inspection of manufacturers’ price lists for some items show discounts larger than those that appear in the Red Book by taking into account not only quantity per retail package, but number of packages per order. Other forms of discount include periodic rebates, extra goods given to the pharmacy by the manufacturer’s representative, returned goods policy used to return slow-moving merchandise in addition to outdated goods, and extended dating of receivables. Special deals are offered intermittently and in certain areas but not others. Some such discounts reflect themselves in invoice prices; others do not.

*Id.* at 4. The report found that similar – though not as steep – discounts were available through wholesalers:

Wholesalers’ discounts to most pharmacies in California appear to range from 8 to 12 percent below AWP. ... These discounts normally apply, not on an item-by-item basis, but to all purchases made during a month or other span of time. ... These discounts usually do not appear on invoices. The discount serves as both a volume and cash discount.

*Id.* at 4-6. On a whole, the report concluded that “[t]he range of discounts among pharmacies is unknown but probably is from 8 to 25 percent or more...” *Id.* at 6. The Report noted that, at the time, EAC for most drugs was an undiscounted AWP and that “[t]he actual acquisition cost of individual pharmacies has no bearing upon the payment Medi-Cal makes.” *Id.* at 23. The 1977 Report also noted that “[s]ome manufacturers maximize pharmacy earnings from Medi-Cal by maximizing the spread between the price charged Medi-Cal (usually based on small quantities) and that paid by pharmacies (often a lower price based on large quantities).” *Id.* at 29. However, the Report recognized that the margins providers realized compensated for inadequate dispensing fees: “Prior to the new EAC controls of March 6, 1977 the margin between AWP and pharmacies’ actual

acquisition cost served to offset a fee level which many pharmacists believed to be inadequate.” *Id.* at 23.

Plaintiffs’ Response: Plaintiffs do not dispute that Defendants have correctly quoted a portion of the 1977 Report. Plaintiffs further incorporate their response to SOF 22.

24. In 1985, HCFA conducted a California-focused study comparing published AWPs to actual acquisition costs available to pharmacists throughout the state. (Robben Decl., Ex. 15.) HCFA published its findings in a report entitled “EAC Survey Report, California Medi-Cal Program, EAC Patrol Initiative”. *Id.* The report noted that “AWPs are not determined by surveying market transactions and thus do not accurately reflect prices pharmacists pay for drug products.” *Id.* at 2. The report also noted that, at the time, California’s EAC was calculated using an undiscounted AWP. *Id.* at 4. The report concluded that California pharmacists acquired drugs at an average of 16.63 percent below AWP. *Id.* at 6. The report also found that California pharmacists purchased generic drugs at an average of 22.14 percent below AWP. *Id.* at 7.

Plaintiffs’ Response: Plaintiffs incorporate their response to SOF 22. Plaintiffs further respond as follows: This statement is disputed in part. It is noteworthy that the 1985 HCFA study examined a very small sample of the many transactions covered by Medi-Cal—only 480 transactions at 20 California pharmacies. (Robben Decl. Ex. 15 at 5, 8.) Further, the report referenced by Defendants makes clear that:

[E]stimated rather than actual acquisition cost reimbursement was adopted as a result of widespread opposition to the potential difficulties pharmacists would incur in recordkeeping and . . . the administrative problems of tracking deferred and cumulative discounts to pharmacists on their drug purchases. The purpose of the EAC requirement in the regulations was to bring reimbursement for drug ingredients more in line with what pharmacists were actually paying in the marketplace for those items.

(Robben Decl. Ex. 15 at 1.) As the report later reaffirmed, “the EAC should reflect the prices pharmacists are actually paying in the marketplace for drugs.” (*Id.* at 9; *see also id.* at 3, noting that the very purpose of the instant study was to bring “EACs closer to what pharmacists pay for drugs.”) The report further noted that “the States have been allowed a great deal of latitude in establishing their EAC programs” (*id.*) and that California “has instituted several innovative cost containment measures,” including the use of State MAICs and payment for certain drugs at

“direct price,” as a result of which the State actually “reimburse[d] providers at 9.08 percent below AWP.” (*Id.* at 8.) Thus, California’s effective reimbursement rate was already “significantly less than AWP.” (*Id.* at 9.)

25. In a February 4, 1986 letter, John Rodriguez, at the time the Deputy Director of Medical Care Services at DHS, acknowledged receipt of this report. (Robben Decl., Ex. 16.) In the letter, Mr. Rodriguez expressed concern about using the findings in the report to adjust California’s EAC. In particular, Mr. Rodriguez noted:

[W]e would like to remind HCFA that successfully “tightening up” our EAC program will concomitantly result in enormous pressure for California’s Medi-Cal program to upgrade the dispensing fee. This is exactly what occurred when we originally implemented our EAC program. Such a development may well result in no significant change in overall drug costs. If, in fact, costs are only shifted, is a change in federal regulations or more aggressive enforcement of existing EAC regulations really cost effective?

*Id.*

Plaintiffs’ Response: Plaintiffs incorporate their responses to SOFs 22 and 24, and further respond that this statement is disputed in part. Defendants have selectively quoted from Mr. Rodriguez’s letter, which also stated that Medi-Cal had concerns regarding the study’s accuracy in that it “did not weight the data, therefore rendering the conclusions of questionable value” and improperly excluded all drugs subject to a federal MAC (now a FUL). (Robben Decl. Ex. 16 at 1.) He also noted that a “significant number of drugs included in the survey are very low dollar volume drugs and their impact on the overall pharmaceutical program is negligible.” (*Id.*) Mr. Rodriguez further commented that “California is one of the leading states in its aggressive implementation of the federal EAC regulations.” (*Id.* at 2.) Notwithstanding Defendants’ quotation, nothing in the letter indicated that California had a policy to cross-subsidize allegedly inadequate dispensing fees by over compensating pharmacists for the costs of the drug products for which Medi-Cal provided reimbursement. (*See* CA SOAF Defs. ¶ 15.)

26. When California adopted HCFA's 1987 FUL regulations, it issued a statement of reasons supporting its adoption of the regulations. (Robben Decl., Ex. 17.) In the addendum to the final statement of reasons, in response to complaints that FULs may adversely impact small business, California noted that the FUL regulations would actually benefit small businesses, while at the same time saving California money, by encouraging the use of low cost generics:

The regulation encourages pharmacists to select from among available alternatives, the drug product which meets the patient's needs and is available within the upper limit. Lower priced generic brands frequently carry a higher margin of profit in comparison to the more costly name brand drug products they compete with. This has the effect of increasing the actual net profit dollars on a smaller gross sale.

*Id.* at addendum 2. To illustrate the point, the addendum compared the reimbursement for a brand drug, Mellaril, with an AWP of \$28.32, and FUL of \$17.48, and an actual purchase price of \$26.06 to the generic version of the drug, which had an AWP of \$10.90, and an actual purchase price of \$5.23. *Id.* at addendum 3. Because of the FUL, the addendum noted that dispensing the brand drug would result in a net loss to the provider of \$12.62, while dispensing the generic would result in a net profit of \$5.67. *Id.* The addendum concluded that the FUL, when combined with the "spread" between the AWP and actual purchase price for the generic drug, benefited both California and the provider:

Not only did the pharmacist increase his margin by \$3.40 when dispensing the generic drug product over the brand name product; but, by placing an upper limit of reimbursement, Medi-Cal saved \$15.15, which is more than 50% of the reimbursement amount for the brand name product.

*Id.* at addendum 4. In preparing the final statement of reasons and the addendum, California relied on several wholesaler catalogs, including a catalog of Geneva Inc. drugs. *Id.* at 2.

Plaintiffs' Response: Plaintiffs incorporate their response to SOF 22. Plaintiffs further respond as follows. This statement is disputed in part. First, Defendants omit the express statement in the Addendum that Medi-Cal will reimburse at AWP when that amount is lower than the product's FUL. "If the selected brand has an AWP at or below the limit [i.e., the FUL], it can be reimbursed by Medi-Cal at the AWP." (Robben Decl. Ex. 17 at Addendum 2.)

Further, nothing in the Final Statement of Reasons or the Addendum supports the submission of inflated AWPs as a means to foster generic substitution or otherwise. The

example used by Defendants is taken out of context and used in a misleading fashion. Defendants omit the crucial fact that the “actual purchase price of \$5.23” in the example is applicable to purchases in bulk (specifically in 1000s), although Medi-Cal reimburses pharmacies, pursuant to applicable regulations, based on the AWP of the most commonly dispensed package size, which is normally a package of 100 pills. Moreover, the \$5.23 actual price relates to bulk purchases through a discount buying group, the California Pharmaceutical Care Network. Thus, the Addendum uses this example to illustrate the fact that, by using prudent business practices (such as buying in bulk and through a discount buying group), pharmacies can still make a profit after implementation of the FULs that were being adopted through this regulatory proceeding. (*Id.* at Addendum 3.) Nothing in the Final Statement of Reasons or Addendum supports the idea that Medi-Cal approved of or authorized the practice of reporting inflated AWPs for generic products in order to encourage generic substitution.

27. In 1989, the Office of Inspector General for the United States Department of Health and Human Services (“HHS-OIG”) issued a report entitled “Use of Average Wholesale Prices in Reimbursing Pharmacies Participating In Medicaid and the Medicare Prescription Drug Program” (the “1989 HHS-OIG Report”). (Robben Decl., Ex. 18.) The report detailed a survey conducted by the HHS-OIG comparing AWPs published in Blue Book and Medi-Span to prices available to pharmacies through national wholesalers. *Id.* at 2. The report found that the average discount off of AWP for all drugs was approximately 15.5 percent, and for multi-source or generic drugs in particular was 18.2 percent. *Id.* at 3. The report found that prices in one wholesaler’s catalog were on average more than 30 percent below AWP. *Id.* The report quoted a wholesaler representative stating “AWP is a meaningless figure” and a Pennsylvania Medicaid official saying that AWP “... just doesn’t mean anything. It has no connection to what pharmacies really purchase the drugs for.” *Id.* at 3-4.

Plaintiffs’ Response: Plaintiffs incorporate their objections to SOF 22 and their response to SOF 24. Plaintiffs also object to the hearsay statements contained in the final two sentences. Plaintiffs further respond that this statement is disputed in part. Plaintiffs note that the 1989 HHS-OIG report appeared to show a decline in spreads between reported AWPs and actual acquisition costs as compared to the spreads found in the 1985 HCFA study discussed in SOF 24

and that the 1989 report did not take into account the effect of California's other cost containment methods, including its use of MAICs and direct price reimbursement.

More importantly, Defendants omit to state that the 1989 HHS-OIG report was a direct predicate for California's revisions to its reimbursement methodology and Regulation Section 51513 in September 1989 pursuant to an extended rulemaking proceeding. (See CA SOAF Defs. ¶ 18.)

28. In 1991, the Auditor General for the State of California issued a report entitled "How Medi-Cal and Other Health Care Providers Manage Their Pharmaceutical Expenditures." (Robben Decl., Ex. 19.) The Auditor's report cited to the 1989 HHS-OIG Report, noting that the report found that pharmacies were purchasing drugs, on average, at 15.5 percent below AWP and that the report "concluded that the AWP was not a meaningful payment level and that it should not be used for making reimbursements." *Id.* at 27. The report goes on to note that, in September of 1989, in response to guidance from HCFA that state Medicaid programs must discount off of AWP for EAC calculations, DHS adopted regulations setting reimbursement at AWP minus five percent for drugs not reimbursed on the basis of direct price. *Id.*

Plaintiffs' Response: Disputed in part. Defendants omit to disclose that the Auditor General's Report (the "Report") states in the sentence following the one quoted: "The inspector general recommended that the HCFA continue to require state Medicaid agencies, such as Medi-Cal to discount the AWP when making program reimbursements." (Robben Decl. Ex. 19 at 27.) In fact, as noted in the quoted portion of the Report, in 1989, DHS, following a formal ratemaking proceeding, revised Section 51513 to reduce its EAC reimbursement rate to AWP-5%. In taking that action, DHS expressly found that, on an overall basis, that rate was the Agency's best estimate of provider acquisition costs: "In other words, the State must come as close as possible to the actual acquisition cost. The AWP-5% program is the State's best estimate of this cost." (See CA SOAF Defs. ¶ 19.) Further, Defendants omit to disclose that OBRA '90 prohibited changes in State reimbursement rates for several years following the issuance of the Report.

Plaintiffs further note that the Report in large measure compared the amounts that Medi-Cal paid to reimburse providers with amounts paid by “major pharmaceutical purchasers” (Robben Decl. Ex. 19 at 4-5), such as the California Department of General Services and the Department of Veterans’ Affairs, a comparison which the Report notes is inherently inappropriate. As the Report concludes:

As we discussed in Chapter 1 of our report, our survey of major pharmaceutical purchasers revealed they use many utilization and price strategies to control the cost of pharmaceuticals. Medi-Cal uses most of the same utilization and price strategies as the major pharmaceutical purchasers in its attempt to stem the increase in its drug expenditures, but not all of the controls the major pharmaceutical purchasers use would be suitable for use by Medi-Cal because of Medi-Cal’s system for delivering services.

(Robben Decl. Ex. 19 at 38.)

29. In 1994 and 1995, the HHS-OIG conducted a California-focused survey of pharmacy acquisition costs for Medi-Cal providers. (Robben Decl., Ex. 20; Ex. 21; Ex. 22.) DHS employees Douglas Hillblom, Allen Fung, and Roy Takeuchi assisted in the survey. (Robben Decl., Ex. 20 at App. 4.)

Plaintiffs’ Response: Disputed in part. By way of clarification, Plaintiffs point out that the survey involved a number of states, including California.

30. In August of 1994, HHS-OIG held a meeting in Richmond, Virginia to discuss the survey and enlist the assistance of various state Medicaid programs. (Robben Decl., Ex. 21.) Allen Fung attended the meeting on behalf of the Medi-Cal program. *Id.* State Medicaid officials at the meeting expressed concern that the review was limited to one aspect of pharmacy reimbursement and indicated that any effort to lower reimbursement for pharmacists’ acquisition costs should also take into account dispensing fee payments. *Id.*

Plaintiffs’ Response: Disputed in part. It is undisputed that some state Medicaid officials expressed such views, but disputed to the extent the statement implies that all such persons expressed such concerns.

31. In September of 1995, HHS-OIG held a second meeting in Richmond, Virginia to report on the survey’s findings. (Robben Decl., Ex. 23.) Douglas Hillblom attended this meeting on behalf of the Medi-Cal program. *Id.* The state Medicaid officials at the meeting indicated that the results of the survey were in line with what they anticipated. *Id.*

Plaintiffs' Response: Undisputed.

32. In May of 1996, HHS-OIG published the results of the California-focused survey in a report entitled "Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the California Department of Health Services" (A-06-95-00062) (the "1996 HHS-OIG Report"). (Robben Decl., Ex. 20.) The 1996 HHS-OIG Report examined over 2600 pharmacy invoices from across the state and found that pharmacists' invoice prices for brand-name or single source drugs were, on average, 17.5 percent below published AWPs and that invoice prices for generic or multi-source drugs were, on average, 41.4 percent below AWP. *Id.* at i. In his response to the report, John Rodriguez hoped that the report would "substantiate DHS' position that current drug ingredient cost reimbursement by the Medi-Cal program does not reflect actual purchasing activity of California pharmacies." *Id.* at App. 4.

Plaintiffs' Response: Disputed in part. Plaintiffs do not dispute the existence of the 1996 OIG study. However, Plaintiffs dispute any characterization of the study as providing a factual basis to establish discovery, notice and/or government knowledge as to any specific manufacturer or drug product. Plaintiffs further note that the former Chief Deputy Director of Health Care Services, Stanley Rosenstein, testified that the 1996 OIG study was considered in California's efforts to figure out "honest prices" so that the appropriate discount off of AWP could be implemented:

Q. Okay. And I appreciate, there are a lot of, like dispensing fee, right, there are a lot of moving parts that have to be balanced. But I guess -- but what I am trying to get at is, did -- did DHS communicate in 1996 to the California Legislature an effort to reduce reimbursement rates that AWP minus 5 didn't reflect actual purchasing activity by California pharmacists?

MR. PAUL: Objection to form.

THE WITNESS: I am not sure in 1996 where we did. We proposed additional reimbursement reductions in pharmacies, coming off of an AWP minus greater amount.

BY MR. BUEKER:

Q. And as a part of -- as a part of justifying that reduction, one of the things that DHS would have communicated to the California Legislature was that the AWP minus 5 didn't reflect actual purchasing activity by California pharmacists, correct?

A. Typically, my testimony when I did it was, that we were trying to get to honest pricing, that we accurately represented the cost of purchasing, and the cost of dispensing. The key was to have accurate pricing that had transparency, that everybody could see and agree to. So when I did the testimony on this, it really came from the perspective of we need to have a good honest price.

Q. Okay. And I am trying to – I understand that. What I am trying to understand is, whether it was ever communicated to the California Legislature that AWP minus 5 didn't reflect the price at which pharmacists in California were actually purchasing pharmaceutical product?

MR. PAUL: Objection. Form.

THE WITNESS: I believe the communication was that that was an excessive reimbursement, so that we could pay at a higher -- or lower price, higher AWP.

BY MR. BUEKER:

Q. Higher discount of AWP?

A. Higher discount and maintain access to care.

(Paul Decl. Ex. 4 (11/6/08 Rule 30(b)(6) CA Dept. of Health Care Servs. (Rosenstein) Dep.) at 98:7-100:8.)

Plaintiffs further note that Mr. Rosenstein testified that *no manufacturer, following publication of the 1996 OIG report, ever came to Medi-Cal to clarify the discrepancies between its reported AWPs and actual provider acquisition costs:*

Q. I think you were showed earlier in the day an exhibit. I think it was Exhibit 5, a 1996 report by the OIG concerning its examination of the discrepancy between AWPs and acquisition costs for generic and branded drugs. Do you recall that?

A. Yes.

Q. To your knowledge, did any manufacturer come to the Medi-Cal program after the OIG issued that report to offer help in reforming its reporting of AWPs?

A. No.

Q. Did any manufacturer come to the program expressing any concern about the implications of that report to your knowledge?

A. Not to my knowledge, and never to me.

(*Id.* at 303:3-18.)

33. In 1996, the California legislature considered revising Medi-Cal's EAC calculation from AWP minus five percent to AWP minus ten percent or Wholesale Acquisition Cost ("WAC") plus seven percent. (Robben Decl., Ex. 24; Ex. 25 at 143:15-147:18.) In response, DHS prepared a document assessing the fiscal impact of the change and weighing its pros and cons. (Robben Decl., Ex. 24.) The document listed the following as the "Pros" to the proposed change:

- Reduces drug expenditures by reducing ingredient cost reimbursement to make it more consistent with the actual acquisition cost of drugs, and other third party payers.
- Would result in General Fund savings.

*Id.* The document also listed the following as the "Cons" to the proposed change:

- Will be opposed by pharmacy providers just as they opposed a previous legislative proposal on this issue.
- Will undermine working relationship between Department of Health Services and the California Pharmacists Association (CPhA) in efforts to develop a regulatory solution that reduces ingredient costs while recognizing other inequities in the reimbursement policies.
- Some pharmacy providers will stop providing services to Medi-Cal beneficiaries because of the reduced payment.

*Id.* Douglas Hillblom, a Pharmacy Consultant with DHS from 1995 to 2000, testified that the "other inequities" referenced in the second bullet point under "Cons" included an inadequate dispensing fee. (Robben Decl., Ex. 25 at 39:12-40:2; 157:4-158:12.) Although it was considered, this methodology was never adopted. *See supra* at ¶ 19-21.

Plaintiffs' Response: Disputed in part. Plaintiffs dispute that the Legislature considered this in 1996. Rather, the referenced document is a Budget Change Proposal for Fiscal Year 1997-98, which has a proposed implementation date of November 1, 1997. It was likely considered, if at all, in 1997. In addition, the cited evidence does not demonstrate the extent to which, if at all, this proposal was ever considered by the Legislature. Rather, the cited testimony reflects that the Legislature asked DHS to suggest potential changes that would result in

budgetary savings and that this proposal was developed in response, listing the potential pros and cons of reducing the budget in this manner. But there is no evidence that it was actually proposed to, much less considered by the Legislature or was anything more than an internal Agency “think piece.” Plaintiffs further note that the proposal would have eliminated California’s use of “direct price” as an element of its reimbursement formula.

By way of further response, Plaintiffs note that Defendants have omitted those portions of Exhibit 24 that demonstrate that the program intended to reimburse providers for estimated drug acquisition costs, but that, due to the lack of transparency in Defendants’ pricing practices as well as the lack of adequate resources, Medi-Cal could not estimate providers’ acquisition costs with any precision. In that regard, Exhibit 24 states as follows:

DHS does not have an ongoing program which monitors the most appropriate formula for reimbursing pharmacy providers for their actual acquisition drug [sic] costs. . . . The proposal to change the pharmacy dispensed drug reimbursement methodology . . . reflects DHS’ estimate as to actual pharmacy drug ingredient acquisition costs. However, this may not be entirely accurate as this methodology was established without validating actual acquisition costs of drugs within each of the wide variety of pharmacy provider types . . . Historically, Medi-Cal drug ingredient cost reimbursement rates have been based on a combination of estimating actual drug ingredient acquisition costs versus what most other third party payers offer in terms of drug ingredient cost reimbursement. This was appropriate ten or even five years ago, but is no longer a valid approach due to increased competition in the provider marketplace. Much of this change in marketplace pressure is due to managed care programs, both public and private. In recent years, continuous changes in the marketplace have resulted in a myriad of prescription drug buying schemes (e.g., various deals made through wholesale vendors, direct purchases from manufacturers, special deals made based on projected sales, prices based on volume purchases, prompt payment discounts, cooperative buying groups, etc.) This has made it very difficult to determine, on average, what drug ingredient acquisition costs are for pharmacy providers in Medi-Cal. . . . DHS has never developed an ongoing investigative approach to the problem addressed in this proposal. Current level of staffing has not been sufficient to accomplish this level of program monitoring.

(Robben Decl. Ex. 24 at 1-3.)

34. Vic Walker, a Pharmacy Consultant with DHS since 1988, indicated that DHS had access to WACs from First DataBank at the time this proposal was under consideration. (Robben Decl., Ex. 26 at 76:1-77:22.)

Plaintiffs' Response: Disputed as stated. Plaintiffs do not dispute that DHS could have obtained reported WACs from First DataBank, but deny the statement to the extent Defendants imply that DHS routinely examined WACs or compared the WACs for Defendants' products to the AWPs of those products. Furthermore, the Rule 30(b)(6) deponent designated to testify on behalf of Medi-Cal testified as follows regarding the fact that California did not have WAC pricing:

Q. Is the WAC for any given NDC available through the RAIS system?

A. No, it is not.

Q. Okay. So it's not for any NDC?

A. No.

\* \* \*

BY MR. PAUL:

Ms. Tooker, why does DHS at the time, DHCS now, not get WAC information from First DataBank?

A. I can't answer that question.

(Paul Decl. Ex. 5 (10/21/08 Rule 30(b)(6) CA Dept. of Health Care Servs. (Tooker) Dep.) at 98:22-99:4, 114:17-21.)

35. In 1999, Vic Walker prepared an analysis of a similar proposal. (Robben Decl., Ex. 27.) His analysis described the proposal as follows:

This proposal changes the method by which pharmacy drug acquisition costs are reimbursed by replacing Average Wholesale Price minus 5% (AWP-5%) and the Direct Price reimbursement elements in the formula with AWP minus X% or Wholesale Acquisition Cost (WAC) plus Y percent, which is lower, on a drug-by-drug basis. This would more closely approximate actual acquisition costs of drugs by pharmacies.

*Id.* Mr. Walker's analysis noted the California-focused 1996 HHS-OIG Report. *Id.* It also noted that it would be advisable to implement the change through legislation, rather than administrative rule making:

This change *can* be implemented through regulation, but the Department does not believe it can sustain the legal challenges to the regulations that will be brought to bear by its opponents. The most certain way to implement a new reimbursement schedule is through legislation.

*Id.* The analysis also noted that political pressure from lobbying groups had blocked implementation of similar measures in the past:

This identical proposal has been made almost every year since the early 1990s, but has been fought to a standstill in every instance by the effective lobbying efforts of the pharmacy provider organizations and beneficiary advocacy organizations. The pharmacy provider organizations oppose these changes because it would result in reduced reimbursement. The beneficiary advocacy organizations oppose them because they might result in reduced pharmacy provider participation.

*Id.* This proposal, like the previous one, was never adopted. *See supra* at ¶ 19-22.

Plaintiffs' Response: Disputed in part. The cited evidence does not demonstrate the extent to which, if at all, this proposal was ever considered by the Legislature. Rather, the cited testimony reflects that the Legislature asked DHS to suggest potential changes that would result in budgetary savings and that this proposal was developed in response, listing the potential pros and cons of reducing the budget in this manner. But there is no evidence that it was actually proposed to, much less considered by the Legislature or was anything more than an internal Agency "think piece." Plaintiffs further note that the proposal would have eliminated California's use of "direct price" as an element of its reimbursement formula. By way of further response, Plaintiffs incorporate their response to SOF 33, and state that in 1999 the Legislature directed DHS to perform a study of pharmaceutical acquisition costs and dispensing costs, so that it could make appropriate adjustments to the reimbursement rate(s). (*See* SOF 41 below and Plaintiffs' response thereto.)

36. In 2000, the California legislature was considering a bill, AB 1915, that would lower Medi-Cal's pharmacy reimbursement rate from AWP minus five percent to AWP minus 15 percent. (Robben Decl., Ex. 28 at 113:1-19; Ex. 29.) In response to the bill, DHS prepared a bill analysis recommending that AB 1915 be opposed. (Robben Decl., Ex. 29.) In the analysis, DHS raised the concern that a decrease in the reimbursement rate could drive providers out of the program, creating serious access issues:

Reducing the Medi-Cal EAC for drugs with AWP minus 5 percent to AWP minus 15 percent would not be merited without first taking steps to determine an appropriate rate of reimbursement. Federal law requires that the state assure that "...payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers..." [Social Security Act Section 1902(a)(30)(A)] which can best be demonstrated through performance of a proper rate study.

If the proposed AWP minus 15 percent were to be implemented, together with the current direct price component, California would be last in drug ingredient cost pharmacy reimbursement when compared to other "AWP minus" states. At this point, Medi-Cal may suffer a serious patient access problem as providers disenroll from Medi-Cal rather than accept the reduced payment.

*Id.* at 2. AB 1915 was never enacted. *See supra* at ¶ 19.

Plaintiffs' Response: Disputed in part. As Exhibits 28 and 29 make clear, DHS's opposition to Assembly Bill 1915 was based on a number of reasons, including, but not limited to those Defendants mention. By way of further response, Plaintiffs' incorporate their responses to SOFs 33 and 25, above, and state that DHS was already in the process of performing a reimbursement rate and dispensing cost study so that it could recommend appropriate changes to the State's reimbursement formula.

37. At their depositions, several Medi-Cal officials testified that they have understood for a long time that AWP was not representative of actual prices paid.

Plaintiffs' Response: Disputed. In addition, Plaintiffs object to this statement as improperly vague and incapable of response, in particular since Defendants cite no supporting evidence. Plaintiffs further respond that certain Medi-Cal officials testified that, although they believed reported AWPs were "not representative of actual prices paid" by pharmacies, they also

testified that various features of California's reimbursement methodology, including the reimbursement of certain manufacturers' drugs at the "direct price" as well as the fact that EAC was discounted from AWP, compensated for the variance between AWP and actual acquisition costs.

38. Kevin Gorospe, Chief of the Medi-Cal Pharmacy Policy Unit at DHS since 2000, testified as follows:

Q. ... You understood that variation -- Sometime in the late nineties you understood that variations existed between how Medicaid was reimbursing for drugs and the actual pharmacy acquisition costs for drugs?

A. Yes.

(Robben Decl., Ex. 30 at 503:13-18.) Mr. Gorospe also acknowledged that prices for generic drugs were generally significantly more than 20 percent below AWP:

Q. Did you have that understanding also going back to the late nineties, that AWP minus 20 percent is significantly higher than pharmacy acquisition costs for generic drugs?

A. Yes.

...

Q... So was it your understanding to the extent you recall this proposal that the reimbursement rate of AWP minus 20 percent was made knowing that reimbursement on that basis would be significantly higher than acquisition costs for generic drugs?

A. Yes.

(Robben Decl., Ex. 30 at 594:7-11; 594:21-595:5.)

Plaintiffs' Response: Plaintiffs do not dispute that Defendants accurately, but selectively, quote excerpts of Dr. Gorospe's testimony. By way of further response, Plaintiffs state that Medi-Cal relied on the accuracy of the price information that Defendants reported and did not have the resources to conduct ongoing audits of pharmaceutical pricing patterns. Plaintiffs further note that Douglas Hillblom, who worked for DHS from 1993 to 2005 and was the Senior Pharmaceutical Consultant from 1995 to 2001, testified as follows:

Q. To your knowledge did the -- during your time at the Department of Health Services did the Department of Health Services have an

expectation that drug manufacturers would report the AWPs to First DataBank honestly and truthfully?

MR. BUEKER: Objection to form.

MS. BERWANGER: Objection to form.

MR. ROBBEN: I thought he wasn't a 30(b)(6) witness.

THE WITNESS: My understanding is that the expectation of the Department was that the -- the data supplied was the appropriate data, that it was accurate.

(Paul Decl. Ex. 6 (9/23/08 Hillblom Dep.) at 348:1-13.) Plaintiffs further note that Dr. Gorospe testified as follows:

BY MR. PAUL:

Q. At any time in your career at DHCS have you ever received any communication of any sort from Mylan explaining the differences between the AWPs it reports and providers' actual acquisition costs?

A. Not that I can recall.

Q. At any time in your career at DHCS have you ever received any communication of any sort from Sandoz explaining the differences between the actual acquisition costs for its drugs and Sandoz's reported AWPs?

A. Not that I can recall.

Q. I won't restate the question each time, but the same question regarding Dey Pharmaceuticals?

A. Not that I recall -- not that I can recall, no.

Q. And Warrick?

A. Again, the answer is no.

Q. Schering?

A. No.

(Paul Decl. Ex. 7 (9/22/08 Gorospe Dep.) at 698:7-699:6.)

Q. In your opinion, Dr. Gorospe, if manufacturers had reported AWPs truthfully as -- as accurate measures of actual wholesale prices, would this legislation and the efforts made to implement it have -- have been necessary?

MR. BUEKER: Objection as to form.

THE WITNESS: If you mean by "truthful" the description as stated here, what wholesale selling price represents?

MR. HENDERSON: Yes.

THE WITNESS: Yes, this legislation would not have been necessary.

(Paul Decl. Ex. 1 (12/3/08 Rule 30(b)(6) Dept. of Health Care Servs. (Gorospe) Dep.) at 253:10-21; *see also* Pls.' Resp. to SOFs 33 and 35 above.)

39. Len Terra, Mr. Gorospe's predecessor, agreed that AWP did not reflect prices actually paid:

Q. Would you have agreed in 1985 that AWP was not a reliable predictor of the price pharmacists actually pay for drugs?

A. I probably would have agreed to that, but I would not have necessarily been privy to this type of information. I am not aware of, you know, being aware of this specific information, but it was generally known in the pharmacist industry that AWP did not reflect actual acquisition costs by pharmacists.

(Robben Decl., Ex. 31 at 107:1-11.)

Plaintiffs' Response: Plaintiffs object to the relevance of this SOF in that this statement relates to Mr. Terra's understanding some nine years prior to the beginning of the relevant period and four years before California extensively studied its reimbursement rates and revised its reimbursement methodology in 1989. Plaintiffs incorporate their responses to SOFs 22, 24, 25 and 38 above. (*See also* CA SOAF Defs. ¶¶ 18-19.)

40. Vic Walker indicated that he understood since 1996 that Medi-Cal's EAC calculation was higher than pharmacists' acquisition costs:

Q. And was there a time after California implemented the AWP-5 percent reimbursement that you reached an understanding that reimbursement based on AWP-5 percent was in excess of pharmacies' actual acquisition cost?

A. I -- at some point I arrived at that conclusion. I don't know when.

Q. It was before this report was issued though; correct?

A. Yes.

Q. Was it well before this report was issued?

A. Well, we have evidence in 1996 I was thinking that way.

(Robben Decl., Ex. 26 at 146:12-147:3.)

Plaintiffs' Response: Disputed in part. Plaintiffs do not dispute that Defendants have correctly, if selectively, quoted Mr. Walker's testimony. Plaintiffs object to this statement on the grounds that Mr. Walker was a Pharmacy Consultant who did not at any time have authority to either speak for DHS or set Agency policy. His personal opinions are therefore irrelevant. By way of further response, Plaintiffs incorporate their responses to SOFs 33, 34, 35, 38 and 39 above and note that the Agency did not have adequate resources to accurately determine pharmaceutical ingredient costs, but instead were forced to rely in large measure on the honesty and integrity of the prices that Defendants reported.

#### **IV. THE MYERS & STAUFFER REPORTS**

41. In 1999, the California legislature required DHS to perform a study of Medi-Cal provider acquisition costs and dispensing costs for pharmaceutical products. (Robben Decl., Ex. 32 at 227:13-18.) DHS commissioned Myers and Stauffer LC to conduct the study. *Id.* at 227:19-228:3.

Plaintiffs' Response: Plaintiffs do not dispute the facts contained in SOF 41, but clarify that California Senate Bill 393 expressly required as follows:

"The State Department of Health Services shall conduct a study of the adequacy of Medi-Cal pharmacy reimbursement rates including the cost of providing prescription drugs and services."

(Robben Decl. Ex. 33, at 3.)

Plaintiffs further clarify that DHS did not have the manpower to conduct such a study itself and was required to issue a request for proposals, part of the government bid process, before eventually selecting Myers & Stauffer to undertake the study and issue its report. In his deposition, Dr. Kevin Gorospe, the Chief of the Medi-Cal Pharmacy Policy Unit, testified that the report took about 18 months to obtain after Myers & Stauffer was engaged to prepare it.

Q. Okay. In 1999 did the California Legislature instruct the Department to prepare a study on the -- the adequacy of reimbursements to pharmacies?

MR. BUEKER: Objection as to form.

THE WITNESS: Pursuant to Senate Bill 393 the Legislature directed the Department to do a study.

BY MR. HENDERSON:

Q. Okay. And was that in 1999?

A. That was in 1999.

Q. Okay. Did -- did the Department take any action within the next year on that?

A. No.

Q. Did the Legislature subsequently establish a deadline for a study -- such a study -- if you recall?

A. Not that I can recall --

Q. Okay.

A. -- specifically.

Q. In any event, did the Department then take some action to have such a study prepared?

A. Yes. In 2001 the Department issued an RFP, Request for Proposal, to find a -- company to do such a study.

Q. All right. And that -- that request for proposal ultimately resulted in an arrangement with Myers and Stauffer, and they produced two reports that have been discussed in your testimony previously; is that right?

A. That's correct. They -- they produced essentially two reports. They were -- one on dispensing costs and one on acquisition costs.

Q. So about how long did it take between when the Department first started the process of preparing a request for proposal and when the Myers and Stauffer studies were actually issued?

A. Roughly 18 months.

(Paul Decl. Ex. 1 (12/3/08 Gorospe Dep.) at 237:21-239:16.)

42. In June of 2002, Myers and Stauffer issued two reports detailing the results of its study. (Robben Decl., Ex. 32 at 227:19-228:22; Ex. 33; Ex. 34.)

Plaintiffs' Response: Plaintiffs dispute that the reports were issued in June 2002, but rather agree that, as stated in SOF 52, the Myers & Stauffer reports, although due on July 1, 2002, were in fact released on August 23, 2002.

43. One report, entitled "A Survey of Acquisition Costs of Pharmaceuticals in the State of California," examined pharmacists' actual acquisition costs for the top 2,000 drugs as measured by Medi-Cal expenditures. (Robben Decl., Ex. 34 at 3.) The report examined invoices from over 2,000 Medi-Cal providers. *Id.*

Plaintiffs' Response: Plaintiffs do not dispute the facts in the first sentence, but dispute the second sentence. On page 10 of the report, the survey methodology indicates a random sample of 2010 pharmacies was asked to participate in the study but usable invoices came from only 491 pharmacies. (Robben Decl. Ex. 34 at 10.)

44. According to the report, pharmacists could acquire single source drugs at an average of 82.8 percent of AWP. (Robben Decl., Ex. 34 at 4) The report also found that pharmacists could acquire multi-source drugs without a FUL for an average of 56.6 percent of AWP. *Id.* Finally, the report concluded that pharmacists could acquire multi-source drugs with a FUL for an average of 12.7 percent of AWP and 38.7 percent of the FUL. *Id.*

Plaintiffs' Response: Plaintiffs dispute Defendants' characterization of the report, which states: "The acquisition costs for multi-source drugs exhibited *much greater variation* but

averaged 56.6% of the AWP (mean weighted by Medi-Cal volume) for drugs without FUL prices." (Robben Decl. Ex. 34 (italics added).)

To clarify by adding context, Dr. Gorospe explained that there would be significant problems if 56.6% of AWP was used for reimbursement of such drugs, as some providers would be undercompensated and some would be overcompensated. The chart indicates the weighted mean with underpayment and overpayment occurring on either side of the mean. Using AWP minus 56.6% would not accomplish California's goals to be fair and consistent in reimbursing for drugs.

Q. All right. I believe the chart indicates that the weighted mean shown in terms of average acquisition cost as a percentage of AWP is 56.6 percent; is that right? That's what this says anyway?

A. That's what the chart says, yes.

Q. And if reimbursement were set at AWP minus 56.6 percent, what would that mean for those drugs that are at the right side of the mean?

MS. DANNA: Object to form.

THE WITNESS: For products whose average acquisition cost is above 56.6 percent that would mean the pharmacy would – would essentially lose money on the ingredient cost.

BY MR. HENDERSON:

Q. Okay. And for drugs to the left of the mean what would it mean for pharmacies who are reimbursed for those drugs?

A. That they would make money based on the percentages.

Q. All right. So if -- would it be fair to say that if -- if reimbursement were based on AWP minus 56.6 percent of AWP, there would be very significant inaccuracies in the amounts of reimbursements because of this wide variation in the relationship between AWP and actual acquisition costs?

MR. BUEKER: Objection as to form.

BY MR. HENDERSON:

Q. Is that fair to conclude?

MR. BUEKER: Same objection.

THE WITNESS: Based on the -- the chart presented, that's correct.

BY MR. HENDERSON:

Q. Are you aware of any rational policy reason for paying inflated reimbursements for those drugs that just happened to fall on the left side of the mean?

MR. BUEKER: Objection as to form.

THE WITNESS: No, I don't.

BY MR. HENDERSON:

Q. And are you aware of any rational policy reason for paying an inadequate ingredient cost for those drugs that happen to be on the right side of that midpoint?

MR. BUEKER: Same objection.

THE WITNESS: No, I don't.

BY MR. HENDERSON:

Q. Is it the Department's policy to be fair and consistent in its methodology for reimbursing drugs?

A. Yes.

(Paul Decl. Ex. 1 (12/3/08 Rule 30(b)(6) CA Dept. of Health Care Servs. (Gorospe) Dep.) at 243:8-245:16.)

45. The report also contained lists comparing average actual acquisition costs to published AWPs for the top 200 multi-source products without a FUL and the top 200 multisource products with a FUL. (Robben Decl., Ex. 34 at Exs. 5 & 6.) Included on these lists are 3 of the Dey subject NDCs, 31 of the Mylan NDCs and 44 Sandoz NDCs. *Id.* The chart below sets forth examples comparing the average actual acquisition costs and published AWPs for certain of the Subject Drugs, as well as the "spreads" between them:

<b>Drug/NDC</b>	<b>Average actual acquisition cost per unit</b>	<b>Published AWP per unit</b>	<b>Spread</b>
<b>Mylan's cimetidine 00378037205</b>	\$0.05	\$1.61	3055%
<b>Mylan's diphenoxylate/atropine 00378041510</b>	\$0.09	\$0.48	419%
<b>Dey's ipratropium 49502068503</b>	\$0.21	\$0.71	238%
<b>Dey's albuterol sulfate 49502069703</b>	\$0.07	\$0.40	471%
<b>Sandoz' Amiodarone HCL 781120360</b>	\$0.57	\$3.13	447%
<b>Sandoz' Atenolol 781150701</b>	\$0.03	\$1.04	3836%

Plaintiffs' Response: Plaintiffs dispute Defendants' implied representation that a column labeled "spread" exists in the multi-paged chart contained in the Myers & Stauffer report. No such column was included in the lists to which Defendants point in SOF 45.

Nevertheless, Plaintiffs do not dispute Defendants' accurate calculations of their own, and acknowledged, megaspreads based on the Myers & Stauffer snapshot of pricing data.

46. Not surprisingly, the report concluded that California's EAC calculation at the time, AWP minus five percent, paid providers considerably more than their actual acquisition cost for drugs:

Findings from this study indicate that the current pharmacy ingredient reimbursement rate of AWP less 5% provides payments in excess of the costs actually incurred by California pharmacies in acquiring pharmaceutical products for Medi-Cal recipients. In fact, the acquisition cost study findings indicate that for a "typical" prescription, a pharmacy's margin on ingredient reimbursement is approximately \$10.

(Robben Decl., Ex. 34 at 4-5.) However, the report warned that the ingredient cost could be assessed without also considering the dispensing fee:

These margins on ingredient cost must be considered in tandem with an analysis of pharmacy dispensing cost and dispensing fee reimbursement.

*Id.* at 5.

Plaintiffs' Response: Plaintiffs dispute Defendants' characterization that the report concluded that providers were paid "considerably more" than actual acquisition costs for all drugs, or that the report "warned" anyone.

Plaintiffs further note that the report did not purport to analyze the legality of considering ingredient costs "in tandem" with dispensing costs, but only the economic reality that together the two items resulted in the "total" reimbursement paid to pharmacies. The 1989 regulatory history made clear that California did not have a policy of cross-subsidizing purportedly inadequate dispensing fees by overcompensating providers for ingredient costs. In addition, Dr. Gorospe testified that California did not permit or approve of inflated reimbursement on ingredient cost to subsidize for supposedly inadequate dispensing fees. (Paul Decl. Ex. 1 (12/3/08 Rule 30(b)(6) CA Dept. of Health Care Servs. (Gorospe Dep.) at 294:6-296:14, 299:3-10.)

California also disputes the implication that the State of California had a policy of paying inflated ingredient costs in order to cross-subsidize dispensing fees. Dr. Gorospe testified on the subject as follows:

BY MR. HENDERSON:

Q. Did the – did the Department ever delegate to drug manufacturers the authority to determine how much dispensing fees should be paid to providers?

A. No.

Q. Did the Department ever take a position that drug manufacturers should be permitted to report false AWP pricing information so that – in order to compensate for inadequate dispensing fees?

MR. BUEKER: Objection as to form.

A. THE WITNESS: No.

BY MR. HENDERSON:

Q. In your opinion, Dr. Gorospe, would it be a reasonable government policy to give drug manufacturers the – the power to increase reimbursements in order to make up for what they perceive to be inadequate dispensing fees?

MR. BUEKER: Objection as to form.

A. HE WITNESS: No.

BY MR. HENDERSON:

Q. Why not?

MR. BUEKER: Same objection.

A. THE WITNESS: Why not what?

BY MR. HENDERSON:

Q. Well, why wouldn't that be a reasonable policy to pursue?

MR. BUEKER: Same objection.

A. THE WITNESS: The management of the – the program is – with the State of California and with – and the federal government, and to allow a – what is considered in California a provider type, which a manufacturer is, to set rates for providers would – would not make sense.

BY MR. HENDERSON:

Q. It would give the manufacturer control over how much money is – of the State's money is spent; is that fair to say?

A. Potentially.

Q. To your knowledge has – Let me withdraw that and ask a different question. If Abbott Laboratories reported grossly inflated Average Wholesale Prices to First DataBank knowing and intending that those prices would be used by state Medicaid agencies, including Medi-Cal, to pay inflated reimbursements to customers, people who bought Abbott drugs, would you consider that to be deceptive?

MR. COLE: Objection. Form.

A. THE WITNESS: Yes.

\* \* \*

Q. Has the Department ever had a – any policy or practice of paying inflated acquisition costs in order to compensate for perceived inadequate dispensing fees?

MR. BUEKER: Objection as to form.

A. THE WITNESS: Was it a policy?

Q. MR. HENDERSON: Yes.

A. THE WITNESS: No.

(Paul Decl. at Ex. 1 (12/3/08 Rule 30(b)(6) CA Dept. of Health Care Servs. (Gorospe) Dep.) at 294:6-296:14, 299:3-10.) In addition, Douglas Hillblom, who worked for DHS from 1993 to 2005 and was the Senior Pharmaceutical Consultant from 1995 to 2001, testified as follows:

A. THE WITNESS: Pharmacy reimbursement is a multi-component item. Cost of the drug product is only one component.

BY MR. BUEKER:

Q. The other component is dispensing fee; correct?

A. Correct.

Q. And that's a rate that was set independently of the ingredient cost reimbursement rate; is that fair?

A. Yes.

Q. And together the two had to total something that the Department considered reasonable; right?

A. Yes.

Q. But in terms of the actual calculation of the two components, the calculation of the two components, that portion of it was done separately?

A. Yes.

Paul Decl. Ex. 6 (9/23/08 Hillblom Dep.) at 93:16 - 94:13.)

47. The second report, entitled “Study of Medi-Cal Pharmacy Reimbursement,” examined Medi-Cal pharmacy providers’ costs to dispense drugs. (Robben Decl., Ex. 33.) The report found that the average cost of dispensing drugs weighted by Medi-Cal volume was \$8.69. *Id.* at 26. Excluding intravenous and compounded drugs, the report found that average cost of dispensing weighted by Medi-Cal volume was \$7.21. *Id.* at 28. Even excluding intravenous drugs, the average cost of dispensing was more than \$3.00 higher than the \$4.05 dispensing fee then paid by California.

Plaintiffs’ Response: Plaintiffs dispute Defendants’ characterization of the Myers & Stauffer findings. In particular, Myers & Stauffer expressly concluded that it was inappropriate to include the generally greater costs associated with intravenous and compounded drugs and that the \$8.69 amount, which included such products, was not appropriate to use as the basis for reimbursement. (Robben Decl. Ex. 33 at 28.) Further, although the Report found that the average cost of dispensing weighted by Medi-Cal volume was \$7.21 per prescription, the Report expressly concluded that “[t]he measurement that is the most ideally suited for determining the typical cost of dispensing prescriptions to Medicaid recipients is the **median weighted by Medi-Cal volume.**” (*Id.* at 25.) That amount was \$6.95 per prescription. (*Id.* at 28.)

48. As part of the report, Myers & Stauffer calculated the total average cost to the pharmacist to dispense the drug (including the pharmacist’s cost to acquire the drug and the pharmacist’s cost to dispense the drug), the average reimbursement payment by Medi-Cal (including the ingredient cost reimbursement and the dispensing fee), and the average margin for various categories of drugs:

	Average Cost	Average Payment	Average Margin	Percent Margin
<b>Brand drugs</b>	\$120.36	\$133.14	\$12.78	9.60%
<b>Generic drugs without FULs</b>	\$28.87	\$38.34	\$9.47	24.70%
<b>Generic drugs with FULs</b>	\$10.46	\$11.73	\$1.27	10.90%

(Robben Decl. Ex. 33 at 50.)

Plaintiffs’ Response: Plaintiffs dispute this statement, which is incomplete. In particular, Plaintiffs note that Defendants’ chart is incomplete and omits relevant information relating to the

facts that certain drugs were reimbursed at direct price and others based on a MAIC, which resulted in an overall margin on reimbursement of only 11%. The actual report provides as follows:

**Table 5.2 Average Margins on Medi-Cal Prescriptions**

Drug Category	Average Cost <sup>1</sup>	Average Payment <sup>2</sup>	Average Margin	Percent Margin
Single Source – Not Paid with Direct Price	\$120.36	\$133.14	\$12.78	9.6%
Single Source – Paid with Direct Price	\$90.92	\$92.66	\$1.74	1.9%
Multi-Source Drugs – Not Paid with Direct Price (no FUL or MAIC)	\$28.87	\$38.34	\$9.47	24.7%
Multi-Source Drugs – Paid with Direct Price (no FUL or MAIC)	\$51.59	\$51.44	(\$0.15)	(0.3%)
Multi-Source Drugs with a Federal Upper Limit (FUL)	\$10.46	\$11.73	\$1.27	10.9%
Multi-Source Drugs with a MAIC	\$9.79	\$11.07	\$1.28	11.6%
<b>All Drug Product Categories</b>	<b>\$53.88</b>	<b>\$60.55</b>	<b>\$6.67</b>	<b>11.0%</b>

(See Robben Decl. Ex. 33 at 50.)

49. Both reports were provided to the California legislature and would have been considered by them in making any determinations regarding pharmacy reimbursement. (Robben Decl., Ex. 32 at 229:1-230:7.)

Plaintiffs' Response: Plaintiffs dispute this statement. The cited testimony states, and Plaintiffs do not dispute, that the Myers & Stauffer reports were provided to legislative staff. Plaintiffs do not dispute that the reports were likely used at some point by the Legislature, but the extent and manner of such use is not clear from the cited testimony. Furthermore, as discussed in response to SOF 50, below, the Myers & Stauffer reports were not available to the Legislature at the time it adopted the 2002 changes in California's reimbursement methodology, but were used in connection with the 2004 changes.

**V. CALIFORNIA'S CHANGES TO ITS REIMBURSEMENT METHODOLOGY AFTER THE MYERS & STAUFFER REPORT**

50. As set forth above, California adjusted the manner in which it calculated EAC twice after the Myers & Stauffer report was issued.

Plaintiffs' Response: This statement is disputed and misleading to the extent it implies that the 2002 legislative changes to California's reimbursement methodology were based on the Myers & Stauffer reports. To the contrary, the 2002 changes in California's reimbursement rate were contained in a budget trailer bill (Assembly Bill 442), which included 106 sections, one of which pertained to this issue. Further, the legislative history demonstrates that the Legislature acted before the issuance of the Myers & Stauffer reports on August 23, 2002, although the bill was not signed into law until shortly thereafter. Specifically, Assembly Bill 442 was approved by the budget committee in May 2002, was voted upon by the Senate in June 2002, and was passed by the Assembly on August 26, 2002, only three days after the Myers & Stauffer study was issued. Substantively, the Myers & Stauffer reports provided part of the basis for the 2004 change in California's reimbursement formula, but were not the basis not for the 2002 change.

51. In response to the legislation enacting the change from AWP minus five percent to AWP minus ten percent, DHS prepared an enrolled bill report that was signed on September 17, 2002. (Robben Decl., Ex. 35.) Enrolled bill reports are used by DHS to make recommendations to the Governor as to whether to sign or veto legislation passed by the California legislature. (Robben Decl., Ex. 32 at 67:1-12.)

Plaintiffs' Response: Undisputed, but Plaintiffs clarify that Assembly Bill 442 (2002) did much more than simply change the Medi-Cal reimbursement rate. (*See* Pls.' Resp. to SOF 50, above.)

52. In discussing the change from AWP minus five percent to AWP minus ten percent, the report notes:

It is often noted that Medi-Cal's rate of AWP-5% is higher than other third-party payers, both in the private and public sectors. Various reviews of pharmacy purchasing indicate that brand name drugs are purchased at approximately AWP-15% to 17% and generic drugs can be purchased at

AWP-40% to 50%. With this in mind, the original May Revision proposed deep cuts in the ingredient cost rate to AWP-10% for brand drugs and AWP-40% for generic drugs. This type of change, however, does not take into account the overall reimbursement (professional fee) rate. The pharmacy industry has indicated that the average cost of dispensing a prescription, in California, ranges from \$6 to \$10. Arkansas Medicaid's rate study concluded that the cost of dispensing a prescription in Arkansas is \$5.08. Considering the significantly higher cost of doing business in California, a \$6 to \$10 per prescription estimate is very realistic. These costs are significantly higher than Medi-Cal's current professional fee of \$4.05.

Pharmacy providers have relied on the margin between acquisition cost and the Medi-Cal ingredient cost reimbursement rate to account for the difference in the actual cost of dispensing a prescription and the Medi-Cal rate of \$4.05.

The California Pharmacists Association (CPhA) contends that pharmacy providers will be unable to provide prescription services [for] Medi-Cal beneficiaries of the rate proposed in the original May Revision; in some cases, forcing independent pharmacies (non-chain) in areas of high Medi-Cal enrollment out of business. This reduction in pharmacy providers would create access problems for the Medi-Cal beneficiary. CPhA believes that this proposal coupled with the implementation of a broader MAIC program and a reinstatement of the 50-cent claim reduction are cuts that the pharmacy provider community will be unable to bear. In recognition of CPhA's contentions, the DHS modified the original May revision proposal to AWP-10% for all drugs.

(Robben Decl., Ex. 35 at 92-93.) The report also noted that the Myers & Stauffer study, which was due on July 1, 2002, was released on August 23, 2002. *Id.* at 93. In the report DHS stated its support for the change. *Id.* at 10-11.

Plaintiffs' Response: It is undisputed that Defendants have correctly quoted a portion of the Enrolled Bill Report. Plaintiffs object, however, to the extent that much of the material quoted by Defendants summarizes positions expressed by the pharmacy industry and/or the California Pharmacists Association and therefore does not reflect the position of DHS (or the Legislature). Plaintiffs further note that the Report was prepared after the release of the Myers & Stauffer study, but that the legislative discussions and actions referenced in the Report occurred before the release of that study. (*See* Pls.'s Resp. to SOF 50, above.)

53. The legislation became law on December 1, 2002.

Plaintiffs' Response: Undisputed.

54. In 2004, the California legislature lowered the EAC calculation to AWP minus 17 percent and raised the dispensing fee to \$7.25.

Plaintiffs' Response: Disputed in part. As stated in SOF 21, the dispensing fee paid for prescriptions for persons in long term care facilities was \$8.00.

55. Originally, DHS had proposed moving EAC to AWP minus 20 percent. (Robben Decl., Ex. 28 at 192:17-193:10; Ex. 36.) In May of 2004, in response to an inquiry from a California Senate Budget Committee staffer, Kevin Gorospe prepared a paper to support the change to AWP minus 20 percent. (Robben Decl., Ex. 28 at 215:20-222:21; Ex. 37.) That document began by noting that, based on confidential discussions with providers and other individuals knowledgeable of provider costs, "it appears that the average pharmacy obtains drugs at Wholesaler Acquisition Cost (WAC) less some percentage that is based on how quickly they pay their invoices . . . The acquisition cost of generic drugs is often lower than this, however, the specific discount was not readily available." (Robben Decl., Ex. 37.) The document indicates that DHS then obtained WAC prices from First DataBank. *Id.* The document then states as follows:

Based on this information, the Department has determined that the AWP is, on average, 26% higher than WAC for brand name drugs and 350% higher than WAC for generic drugs. Based on this information, if the pharmacies are purchasing brand name drugs between WAC and WAC minus 2% and the Department reimburses the pharmacies at AWP minus 20%, on average, the pharmacies have approximately a 1-3% margin (profit) on brand name drugs and 180-182% margin on generic drugs. Using current AWP and WAC prices and utilization volume from 2003, the weighted average margin on drugs would be 3-5%. The overall margin is probably higher because the acquisition cost of generic drugs is likely lower than what is presented in these calculations.

*Id.* The document also proposes an increase in the dispensing fee to \$8.30.

Plaintiffs' Response: Plaintiffs object to the relevance of such internal agency memoranda, particularly given the facts that the e-mail did not purport to state Agency policy and that the reimbursement rate was a legislative issue and was not determined by DHS. Plaintiffs do not dispute that Defendants have accurately quoted a portion of the document, and

do not dispute the statement that the discounts available on generic drugs prices are not readily available.

56. In an e-mail dated June 15, 2004, Kevin Gorospe stated that, based on information he had received from pharmacy providers, he believed “that the current proposal of AWP-20% plus \$8.30 will be too deep of a cut to maintain access, especially in the area of Long Term Care (LTC).” (Robben Decl., Ex. 38.) At the end of the e-mail, Mr. Gorospe laid out three alternative pricing strategies:

1 – Change the rate to AWP-17% + \$7.50 – This rate is close to the M&S, though it doesn’t allow for inflation of costs in the dispensing fee. It provides a level of savings equal to that proposed by the providers of \$42.7 million GF.

2 – Leave proposal at AWP-20% + \$8.30 and give LTC a fee of \$10.30 – This would provide a cushion for the higher cost associated with LTC pharmacy and result in a \$74.2 million GF savings in the BY.

3 – Change to AWP-18% + \$8.30 (\$9.30 for LTC) – This provides for a compromise rate between the original proposal and the level at which providers indicate that they stop taking Medi-Cal patients. This is a \$41.5 million GF savings in the BY.

DHS staff believe that option 3 is the best. It allows for continued margin and is likely at level to maintain access in the program. It does however result in a decrease in savings of \$37.6 million GF in the BY.

*Id.*

Plaintiffs’ Response: Plaintiffs object to the relevance of such internal agency e-mails, particularly given the facts that the e-mail did not purport to state Agency policy and that the reimbursement rate was a legislative issue and was not determined by DHS. Plaintiffs do not dispute that Defendants have accurately quoted a portion of the e-mail.

57. A June 16, 2004 e-mail sent from the e-mail account of Bud Lee stated that, based on feedback from pharmacies, the proposed change to AWP minus 20 percent “may unduly disaffect access, particularly for LTC facility patients and pharmacies providing high volumes of innovator drugs.” (Robben Decl., Ex. 39.) The e-mail proposed adopting AWP minus 17 percent and an increase in the dispensing fee to \$7.50, with an additional 50 cents for long term care pharmacies. *Id.* Under the heading “RATIONALE”, the e-mail stated as follows:

AWP-20% is an arbitrary number, notwithstanding the current proposal from CPhA. AWP-17% is grounded in the Myers and

Stauffer study, a rigorous and reliable \$400,000 analysis that found the acquisition cost of brand-named drugs on average was AWP-17.2%. This will be the most defensible position in the event of litigation.

*Id.*

Plaintiffs' Response: Plaintiffs object to the relevance of such internal agency e-mails, particularly given the facts that the e-mail did not purport to state Agency policy and that the reimbursement rate was a legislative issue and was not determined by DHS. Plaintiffs do not dispute that Defendants have accurately quoted a portion of the e-mail.

58. The fact sheet that DHS prepared for the legislature concerning the proposal noted that AWP minus 17 percent was still considerably higher than providers' costs for generic drugs. "At AWP-17% Medi-Cal will still be overpaying the cost of generic drugs, which pharmacies can purchase at AWP-40% or less." (Robben Decl., Ex. 36.)

Plaintiffs' Response: Plaintiffs object to the relevance of such internal agency memoranda, particularly given the facts that the memoranda did not purport to formally state Agency policy and that the reimbursement rate was a legislative issue and was not determined by DHS. Plaintiffs do not dispute that Defendants have accurately quoted a portion of the document.

59. The reimbursement methodology proposed in this fact sheet was the one the legislature ultimately adopted. *See supra* at ¶19. It is still in effect today.

Plaintiffs' Response: Plaintiffs object to the relevance of this statement insofar as it pertains to the current reimbursement rate, some five years after the relevant period. In addition, Plaintiffs object in that Defendants have not fully and accurately stated the reimbursement changes that were adopted, in particular, California Welfare and Institution Code section 14105.45 also provided for the use of "selling price" as part of the reimbursement formula, which was to be based on an "average sales price" to be reported by manufacturers. (See CA SOAF Defs. ¶¶ 23-24.) In addition, the Legislation made changes to the MAIC program that

were intended to separately address the problem of reported generic drug prices that were grossly inflated over actual prices.

## **VI. THE COMMENCEMENT OF THIS ACTION**

60. This action was originally commenced in July of 1998 by a *qui tam* relator, Ven-A-Care of the Florida Keys, Inc (“Ven-A-Care”). (Robben Decl., Ex. 40; Ex. 41 at 2.) The original *qui tam* complaint was filed under seal and named as defendants 23 drug manufacturers, including Dey, Inc. (Robben Decl., Ex. 41 at 2.)

Plaintiffs’ Response: Undisputed. Plaintiffs further note that the 1998 *qui tam* Ven-A-Care complaint did not name Mylan and/or Sandoz as Defendants.

61. The original *qui tam* complaint sets forth a chart containing the published price, Ven-A-Care’s acquisition cost, and the so-called “spread,” both in percentage and dollar terms, for 11 of Dey’s Subject NDCs. (Robben Decl., Ex. 40 at 105-107.) The alleged “spreads” range from 55 percent to over 500 percent. *Id.* Set forth in the chart below are examples of the [sic] for 2 of the Dey NDCs:

<b>Drug</b>	<b>Ven-A-Care’s Cost (per package)</b>	<b>California’s Payment (per package)</b>	<b>“Spread”</b>
Dey’s cromolyn 49502068902	\$24.50	\$39.90	62%
Dey’s albuterol sulfate 49502069703	\$8.50	\$28.74	238%

Plaintiffs’ Response: Plaintiffs do not dispute the statement that “The alleged spreads range from 55 to over 500 percent.” Note that the “spread” is the “provider’s gross profit %”, which represents the difference between Medi-Cal payment and Plaintiff’s acquisition cost. Medi-Cal was reimbursing at the rate of AWP minus 5% in 1995.

Plaintiffs dispute the statement, “The original *qui tam* complaint sets forth a chart containing the published price, Ven-A-Care’s acquisition cost, and the so-called “spread,” both in percentage and dollar terms, for 11 of Dey’s Subject NDCs.” The chart depicts 14 Dey NDCs

and shows the Medi-cal payment, Plaintiff's acquisition cost, Provider's Gross Profit \$ and Provider's Gross Profit %—not the published price.

Plaintiffs dispute the statement, “Set forth in the chart below are examples of 2 NDCs of Dey drugs,” as incomplete, because Defendants’ chart fails to show the “provider’s gross profit dollars” below.

Cromolyn - Provider’s Gross Profit - \$15.40

Albuterol - Provider’s Gross Profit - \$20.25

62. Ven-A-Care filed an amended *qui tam* complaint in August of 2002, also under seal, which named a total of 46 drug manufacturers, including Dey, Mylan, and Sandoz. (Robben Decl., Ex. 42; Ex. 41 at 4.)

Plaintiffs’ Response: Undisputed.

63. Like the original *qui tam* complaint, the amended *qui tam* complaint contained charts setting the published price, Ven-A-Care’s acquisition cost, and the so-called “spread,” both in percentage and dollar terms for 283 of Mylan’s NDCs (*id.* at 93-117) and for 17 of Sandoz’s Subject NDCs (*id.* at 164). Set forth in the chart below are examples for 2 of the Mylan NDCs and 2 of the Sandoz NDCs:

Drug	Ven-A-Care’s Cost (per package)	California’s Payment (per package)	“Spread”
<b>Mylan’s cimetidine 00378037205</b>	\$32.74	\$765.68	2239%
<b>Mylan’s diphenoxylate/atropine 00378041510</b>	\$165.34	\$422.75	156%
<b>Sandoz’ alprazolam 00781107905</b>	\$7.04	\$453.74	6345%
<b>Sandoz’ fluphenazine HCL 00781143901</b>	\$12.71	\$109.01	378%

Plaintiffs’ Response: Plaintiffs dispute the statement, “Like the original *qui tam* complaint, the amended *qui tam* complaint contained charts setting the published price, Ven-A-Care’s acquisition cost, and the so-called “spread,” both in percentage and dollar terms for 283

of Mylan's NDCs (*id.* at 93-117) and for 17 of Sandoz's Subject NDCs (*id.* at 164)." Instead, the chart sets forth 279 of Mylan's NDCs and shows Medi-Cal payment, Ven-A-Care's cost, Gross Profit \$ spread and Spread as % of actual cost. It did not show the "published price."

Plaintiffs dispute the completeness of Defendants' representations concerning the charts, as follows:

Mylan Cimetidine – Provider's Gross Profit \$732.94 Spread is omitted.

Mylan Diphenoxylate – Provider's Gross Profit \$257.41 Spread is omitted.

Sandoz Alprazolam – Provider's Gross Profit \$446.70 Spread is omitted.

Sandoz Fluphenazine –Provider's Gross Profit \$96.30 Spread is omitted and also the Spread as % of Actual Cost is wrong. The spread contained on Plaintiff's chart is 758%.

(Robben Decl. Ex. 41 at 77.)

For clarity, Plaintiffs further note that the "spread" percentage is different from the alleged "spread" in the Dey charts in the original July 28, 1998 complaint. The spreads in the Dey charts were spreads between Medi-Cal prices (AWP minus 5%) and Ven-A-Care's acquisition costs. The Mylan and Sandoz spreads represent the spread percentage between the provider's gross profit and actual cost—NOT Medi-Cal's payment and actual cost, which would have been greater.

64. The action remained under seal as to Dey, Mylan, and Sandoz, until August of 2005, when California filed its complaint in intervention. (Robben Decl., Ex. 1.)

Plaintiffs' Response: Undisputed.

## VII. CHALLENGES TO CALIFORNIA'S REIMBURSEMENT METHODOLOGY

65. On January 16, 2009, a group of pharmacists and other Medicaid providers commenced an action in the United States District Court for the Central District of California entitled *Managed Pharmacy Care v. David Maxwell-Jolly*, No. 09-00382-CAS-MAN. In the action, the providers seek to enjoin the current director of the California Department of Health and Human Services from implementing sections of the legislation AB 1183 that would implement a five percent reduction in pharmacy reimbursement payments to

Medi-Cal providers. (Robben Decl., Ex. 43 at 1-2.) The providers contend that the five percent reduction, the legislature's conduct in enacting it, and the director's conduct in implementing it, are inconsistent with and in violation of federal law governing Medicaid reimbursement payments. (Robben Decl., Ex. 44, at 3-4.) In particular, the providers contend that the five percent reduction violates 42 U.S.C. 1396a(a)(30)(A), which requires that state Medicaid programs make sure that their reimbursement payments are "consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area." *Id.*

Plaintiffs' Response: Plaintiffs dispute SOF 65 to the extent it improperly identifies the Department of Health and Human Services and its director as a party to *Managed Pharmacy Care v. David Maxwell-Jolly*, No. 09-00382-CAS-MAN. The suit was directed toward David Maxwell-Jolly, Director of Department of Health Care Services. (Robben Decl. Ex. 43 at 1-2.) Plaintiffs do not dispute the balance of SOF 65.

66. On February 2, 2009, the providers moved for a preliminary injunction to enjoin the five percent rate cut. (Robben Decl., Ex. 44.)

Plaintiffs' Response: Undisputed.

67. On February 11, 2009, Maxwell-Jolly filed an opposition to the providers' preliminary injunction motion. (Robben Decl., Ex. 43.) The opposition papers filed by Maxwell-Jolly include a declaration of Kevin Gorospe. (Robben Decl., Ex. 43; Ex. 45.) The declaration contains the following paragraph in response to contentions in the providers' motion that the current dispensing fee of \$7.25 does not accurately reflect the cost of dispensing the drugs:

Mr. Wilson next alleges that there is a difference between the Medi-Cal dispensing fee and the average Medi-Cal dispensing cost of \$4.61 per prescription. Actually the difference between the inflated average dispensing cost per prescription of \$11.59 and the 5% reduced Medi-Cal dispensing fee is \$4.71. But as explained in at [sic] pages 9-10 of the DHCS Analysis, the median dispensing fee cost is \$11.01. That means half the pharmacies have a dispensing fee cost [sic] below that amount. Obviously then more efficient pharmacies will not have as great a spread between their dispensing cost per prescription and Medi-Cal dispensing fee. More importantly, for each drug dispensed, Medi-Cal pays not only the dispensing fee but also an amount for the drug itself. And it is because the Medi-Cal reimbursement for the drug itself frequently is well above pharmacy acquisition cost, that any loss on the dispensing fee portion of

reimbursement is made up for by a significant profit on Medi-Cal reimbursement for the drug itself.

*Id.* at ¶ 21.

Plaintiffs' Response: Defendants have accurately quoted a portion of Dr. Gorospe's cited declaration. Plaintiffs dispute, however, Defendants' implication that California had a policy of cross-subsidizing drug dispensing fees through inflated reimbursement for drug ingredient costs. Dr. Gorospe testified that California did not approve of or permit inflated reimbursement on ingredient cost to subsidize for supposedly inadequate dispensing fees. (Paul Decl. Ex. 8 (3/19/08 Gorospe Dep.) at 357:16-358:5; Paul Decl. Ex. 1 (12/3/08 Rule 30(b)(6) CA Dept. of Health Care Servs. (Gorospe) Dep.) at 294:6-296:1, 299:3-10; Paul Decl. Ex. 4 (11/6/08 Rule 30(b)(6) CA Dept. of Health Care Servs. (Rosenstein) Dep.) at 313:10-314:3.) Specifically, with regard to the issue of cross-subsidization, Dr. Gorospe testified:

By Mr. Gobena:

Q: Was it ever, based on your knowledge, was it ever Medi-Cal's policy to overpay for drug ingredient costs?

A. No.

Q. Now, you mentioned -- hold on a second. And was it ever, to your knowledge -- again, was it ever Medi-Cal's policy to knowingly or intentionally overpay providers for drug purchases in order to subsidize what were perceived to be inadequate dispensing fees?

MR. COLE: Object to the form.

THE WITNESS: Not to my knowledge.

(Paul Decl. Ex. 8 (3/19/08 Gorospe Dep.) at 357:16-358:5.)

BY MR. HENDERSON:

Q. Did the—did the Department ever delegate to drug manufacturers the authority to determine how much dispensing fees should be paid to providers?

A. No.

Q. Did the Department ever take a position that drug manufacturers should be permitted to report false AWP pricing information so that—in order to compensate for inadequate dispensing fees?

MR. BUEKER: Objection as to form.

A. THE WITNESS: No.

BY MR. HENDERSON:

Q. In your opinion, Dr. Gorospe, would it be a reasonable government policy to give drug manufacturers the—the power to increase reimbursements in order to make up for what they perceive to be inadequate dispensing fees?

MR. BUEKER: Objection as to form.

A. THE WITNESS: No.

BY MR. HENDERSON:

Q. Why not?

MR. BUEKER: Same objection.

A. THE WITNESS: Why not what?

BY MR. HENDERSON:

Q. Well, why wouldn't that be a reasonable policy to pursue?

MR. BUEKER: Same objection.

A. THE WITNESS: The management of the—the program is—with the State of California and with—and the federal government, and to allow a—what is considered in California a provider type, which a manufacturer is, to set rates for providers would—would not make sense.

BY MR. HENDERSON:

Q. It would give the manufacturer control over how much money is – of the State's money is spent; is that fair to say?

A. Potentially

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BY MR. HENDERSON:

Q. Has the Department ever had a -- any policy or practice of paying inflated acquisition costs in order to compensate for perceived inadequate dispensing fees?

MR. BUEKER: Objection as to form.

THE WITNESS: Was it a policy?

MR. HENDERSON: Yes.

THE WITNESS: No.

(Paul Decl. Ex. 1 (12/3/08 Rule 30(b)(6) CA Dept. of Health Care Servs. (Gorospe) Dep.) at 294:6-296:1, 299:3-10.)

By Mr. Paul:

Q. Just to be clear, I want to confirm with you whether or not, has it ever been the policy of the Medi-Cal program to deliberately accept inflated and inaccurate AWPs simply because the program knew it would offset them by shorting or minimizing the amount of the filling fee for pharmacists?

Mr. Bueker: Objection as to form.

Mr. Cyr: Objection.

A: No. It has always been our policy to have accurate information and to use that information to establish what the accurate price should be, should be on both ends of the equation. We do believe they need to be both looked at, but they have got to come from accurate data sources.

(Paul Decl. Ex. 4 (11/6/08 Rule 30(b)(6) CA Dept. of Health Care Servs. (Rosenstein) Dep.) at 313:10-314:3.)

68. The court presiding over the case granted the providers' motion for a preliminary injunction on February 27, 2009. (Robben Decl., Ex. 46.)

Plaintiffs' Response: Undisputed.

## **VIII. FULS ESTABLISHED BY CMS**

- A. The FULs CMS Set Did Not Comport With the Formula Set Forth in the Regulations**
69. As a general rule, CMS did not adhere to the formula prescribed in 42 C.F.R. 447.332 (2006) when establishing FULs.

Plaintiffs' Response: Disputed. Defendants fail to provide any factual support or citation to support this statement. Sue Gaston, a CMS employee responsible for setting FULs, declared that, “[A]mong my responsibilities as lead analyst for the FUL program was the setting of FULs. My general practice in establishing FULs was that, once I established that there were three suppliers for the drug, I set the FUL at 150 percent of the lowest published price...To the extent I exercised this discretion when setting a FUL, I did so in order to ensure access while also achieving cost savings for the Medicaid program as required by 42 C.F.R. § 447.332.” (Paul Decl. Ex. 9 (Declaration of Susan E. Gaston dated June 15, 2009) at 3.)

70. Sue Gaston was the CMS employee responsible for setting FULs from April 1991 through February of 2003. (Robben Decl., Ex. 47 at 40:7-10, 45:2-12.)

Plaintiffs' Response: Undisputed.

71. Gail Sexton was the CMS employee responsible for setting FULs beginning in November, 2004. (Robben Decl., Ex. 48 at 49:13-50:21.)

Plaintiffs' Response: Undisputed.

72. Although Ms. Gaston and Ms. Sexton were only examined on nine drugs that were selected for targeted FUL discovery, Ms. Sexton testified those nine drugs are not unique, and that the process used to set the FULs for these drugs is representative of the process for establishing FULs more generally. (Robben Decl., Ex. 48 at 31:4-22, 33:1-9.)

Plaintiffs' Response: Undisputed.

73. Ms. Gaston and Ms. Sexton testified that CMS used a computer program (“the FULs System”) to gather both Orange Book data and pricing data from the three national compendia and to initially calculate FULs for those drugs that met the specified criteria. Then, CMS officials would engage in a “manual review” process because “we want to make sure that that lowest price is a true price.” (Robben Decl., Ex. 47 at 232:22-241:7; Robben Decl., Ex. 12 at 410:14-411:18, 416:10-15, 429:18-22, 432:14-21, 533:5-10; Robben Decl., Ex. 48 at 89:2-5, 93:12-94:13 (stating that Ms. Sexton conducted “further manual interventions” into the FUL for albuterol – one of the Subject Drugs – because she had “learned of other suppliers that were marketing this drug”); *id.* at 95:15-95:20 (stating that she would conduct a manual review “in cases where I saw that manual intervention could have changed the price, changed the federal upper limit, or where it appeared that perhaps the criteria was not met and that further intervention should have been taken”); *id.* at 138:6-7 (“When possible we would manually verify that drugs were available.”); *id.* at 147:8-15 (stating that upon finding “an outlier situation” she would

“do some manual verifications on whether that NDC was available and available at that price”)).

Plaintiffs’ Response: Disputed. First, CMS officials testified that they did not engage in a manual review process every time a FUL was established, and that a manual review would be performed only if it was necessary. (Robben Decl. Ex. 12 at 533:5-10; Robben Decl. Ex. 48 at 95:10-20.)

Second, Plaintiffs emphasize that their theory of recovery and damages model are *not* based upon a showing that Defendants’ false price statements caused inflated FULs per se; rather, Plaintiffs contend that Defendants’ false price representations caused California’s computation of the estimate acquisition cost to be inflated (under California’s “lowest of” reimbursement methodology), and thereby caused damages whenever a pharmacy claim’s original reimbursement amount—whether based on AWP, FUL, or U&C—was higher than it would have been but for the Defendants’ false and inflated AWPs. When the Defendants published false and inflated AWPs, they ensured that any claims for reimbursement for their drugs would be false, including all instances in which the but-for “real” AWPs were *less* than the FUL or U&C on which such claims were paid. In other words, had Defendants reported AWPs that reasonably reflected providers’ acquisition costs, those AWPs would have controlled the payment level in all instances in which they were less than the FUL or U&C. Defendants’ false AWPs were therefore material to all instances in which California reimbursed a claim based on the reported AWPs; and were also material to all claims paid by Medi-Cal when the underlying NDC’s actual but-for price, if it had been truthfully reported as the AWP, was lower than the FUL or U&C on which the claim was paid.

Third, while Plaintiffs do not dispute that Ms. Gaston and Ms. Sexton testified as described, the quoted snippets of testimony present an incomplete description of the mechanics

of the FUL-setting process. CMS utilized a computerized application with processing logic that automatically excludes certain NDCs from consideration in establishing a FUL. For example, drug products of labelers who do not have an active Rebate Agreement with the Secretary are excluded from the FULs System output made available to the FULs analyst for consideration in setting an FUL. This processing step reflects the determination of CMS that a FUL should not be calculated based on a price for a product that is not eligible for reimbursement under the Medicaid program. *See* 52 Fed. Reg. at 28653 (“The upper limits for drugs contained in this rule pertain only to the Medicaid program.”). Further, if an NDC is designated by Medi-Span as “inactive” or “deleted,” or designated by First DataBank as “obsolete,” then the FULs System places the record on an “Inactive List” and excludes it from the data output considered by the system user in setting FULs. (Paul Decl. Ex. 10 (Declaration of Dona M. Coffman dated November 25, 2009) ¶ 14.) Moreover, the FUL regulation requires that FULs be based on cost information “for drugs available for sale nationally,” 42 C.F.R. § 447.332(a)(1)(ii) (2006), and thus it would not be proper to set FULs on the basis of prices of drugs that are, or soon will be no longer sold nationally. Finally, if two out of the three Compendia specify that the NDC is a unit dose form of the drug, the FULs System processing logic excludes the NDC from consideration in setting FULs. Plaintiffs do not dispute that CMS employees then manually reviewed the FULs System output to ensure that the final FUL was consistent with CMS’s program objectives. For prices that were important to the determination of a FUL, the FULs analyst typically contacted the manufacturers to verify that the prices are valid and that the products were widely available in the market. Handwritten notes on the printouts illustrate this practice. As explained in the Declaration of Susan E. Gaston dated June 15, 2009 (Paul Decl. Ex. 9), for at least some FULs, CMS has exercised discretion to ensure that the FUL was higher than published WACs of 3

available products of at least three manufacturers. This discretion was exercised to ensure beneficiary access to the drugs while still also achieving cost savings for the Medicaid program. Thus, if the FUL calculated from the lowest published price was not higher than the WACs of at least three manufacturers (including the WAC used to calculate the FUL), then CMS might reject the lowest price (treating it, in effect, as an outlier) and instead calculate the FUL based on the next higher price that would yield a FUL that was higher than at least three WACs for available products. (Paul Decl. Ex. 9 (Gaston Decl.) ¶ 5.)

If a price published in the compendia was significantly lower than other prices, a FULs analyst might call the supplier to verify that the price was actually available, and if so, use that price to set the FUL. (Robben Decl. Ex. 48 at 158:1-15.)

A system upgrade deployed in 1999 gives the FULs analyst limited ability to affect the output of the FULs System. First, the upgrade allows the FULs analyst to annotate the FULs System data by assigning a “T” or “P” exclusion code to an NDC indicate that the product is temporarily or permanently unavailable (typically based on the analyst’s communications with the manufacturer as previously noted). Products with these designations still appear on the FULs on-line System and printouts but will not be considered when the FUL is set. Second, the FULs analyst has the ability to redesignate an NDC to a Product Group in the event the analyst learns of an error in the FULs System matching process. With these two limited exceptions, the FULs analyst does not exercise discretion to include or exclude products from the list that appears in the FULs System printout. (Paul Decl. Ex. 10 (Coffman Decl.) ¶ 17.)

74. Ms. Gaston further testified that the manual review was used to determine whether a drug was “truly available or not” and whether or not “you should follow up and see if it’s available.” (Robben Decl., Ex. 47 at 229:8-230:14.)

Plaintiffs’ Response: Disputed. Plaintiffs incorporate by reference their response to SOF  
73. Additionally, Ms. Gaston testified that she engaged in a manual review when the drug with

the lowest published price was not available and when there was a question as to whether the published price information was correct. (*See Robben Decl. Ex. 47 at 255:18-257:12.*) Such action was necessary given the objectives of the FUL program. (*See id.* at 216:14-19, 245:12-246:16; Robben Decl. Ex. 12 at 329:10-331:3.)

75. During her deposition, Ms. Gaston was presented with the 2001 FULs System printout for clonazepam, one of the Subject Drugs, on which someone had crossed out the FUL generated by the FULs System, \$0.1199, and written in a different, higher FUL, \$0.2455. (Robben Decl., Ex. 12 at 441:22-443:4 & Ex. 5.)

Plaintiffs' Response: Plaintiffs dispute Defendants' incomplete characterization of the testimony. At her deposition, Ms. Gaston testified that the difference between lowest published WAC (\$0.0799) and the next lowest WAC (\$0.16370) caused CMS to believe that setting the FUL on the lowest published WAC would have created an unreasonably low FUL. (*See Robben Decl. Ex. 12 at 444:16-445:13 & Ex. 5.*) (“Q: Do you know why CMS chose not to set a FUL on the basis of that lower published price? A: I could give you my opinion. Q: Sure. A: That here again what I think they were trying to do was since there's such a difference between the .07 and then the next price of .16370, that we wanted to make sure that the FUL price that's set is a reasonable price and that we'll be assured the availability of the drug. So we went up to the next lowest price.”). Plaintiffs further incorporate by reference their response to SOF 73.

76. Ms. Gaston testified that the lowest published price was not used when setting the FUL for clonazepam because CMS “wanted to make sure that the FUL price that's set is a reasonable price and that we'll be assured the availability of the drug” and that therefore “we went up to the next lowest price.” (Robben Decl., Ex. 12 at 442:21-445:4.)

Plaintiffs' Response: Plaintiffs do not dispute this statement, but incorporate by reference their response to SOF 73.

77. During her deposition, Ms. Gaston was presented with the 2001 FULs System printout for lorazepam, another Subject Drug, on which someone had crossed out the FUL generated by the FULs System, \$0.2999, and written in a different, higher FUL, \$0.5718. (Robben Decl., Ex. 12 at 445:14-450:20 & Ex. 6.)

Plaintiffs' Response: Plaintiffs do not dispute this statement, but incorporate by reference their response to SOF 73.

78. Ms. Gaston testified that CMS used a price other than the lowest published price for lorazepam as the basis for the FUL to ensure that the FUL was set at a “reasonable” level. (Robben Decl., Ex. 12 at 450:6-453:1.)

Plaintiffs' Response: Plaintiffs do not dispute this statement, but incorporate by reference their response to SOF 73.

79. During her deposition, Ms. Gaston was presented with the 2001 FULs System printout for cefadroxil, on which someone had crossed out the FUL generated by the FULs System, \$1.2749, and written in a different, higher FUL, \$2.9000. (Robben Decl., Ex. 12 at 453:12-454:20 & Ex. 7.)

Plaintiffs' Response: Plaintiffs do not dispute this statement, but incorporate by reference their response to SOF 73.

80. Ms. Gaston testified that the FUL for cefadroxil that had been calculated by the FULs System required “some manual review” because the price on which it had been based “seemed much lower than all the other published prices.” (Robben Decl., Ex. 12 at 455:6-12.)

Plaintiffs' Response: Plaintiffs do not dispute this statement, but incorporate by reference their response to SOF 73.

81. During her deposition, Ms. Gaston was presented with the 2001 FULs System printout for metoprolol tartrate, another Subject Drug, which showed a FUL generated by the FULs System of \$0.0816 and a handwritten notation that the “new FUL” was \$0.0914. (Robben Decl., Ex. 12 at 419:18-22 & Ex. 2.)

Plaintiffs' Response: Plaintiffs do not dispute this statement, but incorporate by reference their response to SOF 73.

82. Ms. Gaston testified that CMS did not use a lower published price to calculate the FUL for metoprolol tartrate because it had discovered that the manufacturer that had reported that lower price was “temporarily out of stock” and that a FUL resulting from that price “might not be a realistic price.” (Robben Decl., Ex. 12 at 425:15-427:20.)

Plaintiffs' Response: Plaintiffs do not dispute this statement, but incorporate by reference their response to SOF 73.

83. Ms. Sexton testified that, in February of 2005, the FULs System calculated a FUL for lorazepam, another Subject Drug, based on a published price of \$0.077, but that Ms. Sexton chose not to change the previous FUL, which had been based on a published price of \$0.3812. (Robben Decl., Ex. 48 at 126:14-128:11.)

Plaintiffs' Response: Plaintiffs do not dispute this statement, but incorporate by reference their response to SOF 73.

84. Ms. Gaston testified that when she was setting FULs, she could base FULs on B-rated drugs, rather than A-rated drugs, as long as three A-rated drugs were listed in the Orange Book. (Robben Decl., Ex. 12 at 523:15-524:11, 525:8-13.)

Plaintiffs' Response: Plaintiffs dispute that this constitutes a material fact. Plaintiffs do not otherwise dispute this statement, but incorporate by reference their response to SOF 73.

85. Ms. Sexton testified that, when she set a FUL for a particular drug, she would consider drugs that were not listed as A-rated in the Orange Book, and set the FUL according to that price. (Robben Decl., Ex. 48 at 104:4-18) (regarding the FUL for the 90 mcg. albuterol inhaler, a Subject Drug).

Plaintiffs' Response: Plaintiffs dispute that this constitutes a material fact. Plaintiffs do not otherwise dispute this statement, but incorporate by reference the response to SOF 73.

86. Ms. Gaston testified that when CMS set the FUL for cefadroxil, the FUL was not based on the most common package size. (Robben Decl., Ex. 12 at 466:19- 469:14)(recognizing that while the most common package size was found to be the 100-count of cefadroxil, the FUL had been set on the 50-count package size).

Plaintiffs' Response: Plaintiffs dispute that this constitutes a material fact. Plaintiffs do not otherwise dispute this statement, but incorporate by reference their response to SOF 73.

87. Ms. Sexton testified that, when she set the FUL for isosorbide mononitrate, a Subject Drug, she called the manufacturer to determine their unpublished WAC price and set the FUL according to that information. (Robben Decl., Ex. 48 at 113:20-113:21, 117:12-118:3.)

Plaintiffs' Response: Plaintiffs do not dispute this statement, but incorporate by reference their response to SOF 73.

88. Ms. Gaston testified that CMS removed the FUL for the 90 MCG albuterol inhaler upon learning of a shortage of the drug's raw material because "if the product is not available

then it wouldn't make sense to put a FUL price on it." (Robben Decl., Ex. 12 at 470:7-472:21.)

Plaintiffs' Response: Plaintiffs do not dispute that Ms. Gaston testified that CMS temporarily removed the FUL for the 90 MCG albuterol inhaler upon being told by persons outside CMS that there was a raw material shortage for the drug. Furthermore, the FUL regulation requires that FULs be based on cost information "for drugs available for sale nationally," 42 C.F.R. § 447.332(a)(1)(ii) (2006), and thus it would not be proper to set FULs on the basis of prices of drugs that are, or soon will be no longer sold nationally.

89. Ms. Gaston testified that CMS officials would not use a particular published price if that manufacturer "only distribute[d] to maybe [a] limited amount of states and not all states." (Robben Decl., Ex. 12 at 429:9-17.)

Plaintiffs' Response: Plaintiffs incorporate by reference their response to SOF 88 above.

90. CMS officials would decline to set a FUL when the FUL was equal to an AWP because States' "regular reimbursement methodology would be a percentage off of AWP," such that setting a FUL that was equal to AWP "would kind of counter what the states were doing with their other reimbursement methodology." (Robben Decl., Ex. 12 at 456:10-20 (discussing the FUL for cefadroxil); *see also* Robben Decl., Ex. 48 at 76:20-77:13 (stating that she could not recall ever having set a FUL based on an AWP). Ms. Gaston testified that CMS "wouldn't have used AWP" when establishing FULs because "[s]etting a FUL using the AWP wouldn't achieve the cost savings." (Robben Decl., Ex. 12 at 458:15-459:7; *see also* Robben Decl., Ex. 48 at 58:15-59:8 ("[I]f the federal upper limit, once it was calculated, was higher than the AWP price or the majority of the AWP prices, then we would generally not set a FUL on those drug ingredients, because the AWP – well, a couple years ago the average AWP on a national basis was I think AWP minus 12 percent for drug reimbursement, estimated acquisition costs for drug reimbursement for a drug that did not have a federal upper limit."))).

Plaintiffs' Response: Plaintiffs do not dispute this statement, but incorporate by reference their response to SOF 73.

91. CMS did not have any written policy in place for employees to follow in setting FULs, and CMS officials individually made decisions about whether and at what rate to set a FUL on a case-by-case basis. (Robben Decl., Ex. 47 at 250:2-6, 252:3-20; Robben Decl., Ex. 12 at 464:7-465:16; Robben Decl., Ex. 48 at 60:22-61:7.)

Plaintiffs' Response: Disputed. The testimony cited by Defendants does not state that CMS did not have any written policy for setting FULs. (Robben Decl. Ex. 47 at 250:2-6, 252:3-20; Robben Decl. Ex. 12 at 464:7-465:16; Robben Decl. Ex 48 at 60:22-61:7.)

Plaintiffs further dispute that CMS did not have a written policy in place for employees to follow in setting FULs, and that CMS officials individually made decisions about whether and at what rate to set a FUL. Section 447.332 provides:

Upper limits for multiple source drugs.(b) *Specific upper limits.* The agency's payments for multiple source drugs identified and listed in accordance with paragraph (a) of this section must not exceed, in the aggregate, payment levels determined by applying for each drug entity a reasonable dispensing fee established by the agency plus an amount established by CMS that is equal to 150 percent of the published price for the least costly therapeutic equivalent (using all available national compendia) that can be purchased by pharmacists in quantities of 100 tablets or capsules (or, if the drug is not commonly available in quantities of 100, the package size commonly listed) or, in the case of liquids, the commonly listed size.

(*See also* Pls.' Resp. to SOF 73.)

92. Based on FDA data, ipratropium bromide inhalation solution was qualified to be considered for inclusion on the FUL list in 2000, but was not added to the FUL list until August 24, 2003. (Robben Decl., Ex. 12 at 539:19-545:7; Robben Decl., Ex. 49 at ii.)

Plaintiffs' Response: Plaintiffs do not dispute that ipratropium bromide inhalation solution was qualified to be considered for inclusion on the FUL list in 2000 based on FDA data. Based on the FUL setting process, ipratropium bromide inhalation solution was not qualified to be considered for inclusion on the FUL list in 2000. However, Plaintiffs notes that the FULs System does not simply download and reproduce all pricing data published by the compendia. Rather, the System downloads, processes, and groups that data in accordance with criteria designed by CMS to comport with the governing regulation and to further the objectives of the FUL program. (Paul Decl. Ex. 10 (Coffman Decl.) ¶¶ 8-10, 14-15.) The output of this data processing made available to the FULs analyst, who then manually reviews the printouts and

determines final FULs. (*Id.* ¶¶ 16-17.) Plaintiffs further incorporate by reference their response to SOF 73.

**B. CMS Set FULs To Strike a Balance Between Cost-Savings and Access**

93. CMS officials were informally taught by other CMS officials how to exercise their discretion to set FULs manually so as to meet the dual objectives of cost savings and access. (Robben Decl., Ex. 47 at 225:16-226:7; Robben Decl., Ex. 48 at 73:14-74:22.)

Plaintiffs' Response: Disputed insofar as the cited authority does not support this paragraph. The testimony cited by Defendants does not state that CMS officials were “informally taught” by other CMS officials. (Robben Decl. Ex. 47 at 225:16-226:7; Robben Decl. Ex. 48 at 73:14-74:22.) Plaintiffs further incorporate by reference the response to SOF 73.

94. When asked about CMS’s objectives when establishing FULs, Sue Gaston testified as follows:

Q. So what we see in Exhibit 6 is another situation in which, exercising its discretion, CMS chose to set a FUL not based on the lowest published price but based on the next lowest published price because that’s what was reasonable to do in terms of ensuring access, correct?

A. Correct.

(Robben Decl., Ex. 12 at 451:12-19.)

Plaintiffs' Response: Plaintiffs do not dispute that Ms. Gaston testified as noted, but in the interests of completeness, incorporate their response to SOF 73.

95. Ms. Gaston further testified as follows:

Q. So as we’ve kind of seen throughout, CMS is trying to establish a FUL that’s not too low and not too high to achieve a cost savings, but also not set it too low to create an access issue; that’s the balance CMS is trying to strike?

A. Correct.

Q. And you did that – the balance was struck, sometimes the computer program worked as it was supposed to and that balance was struck by the computer program, but other times it was the result of manual intervention?

A. Correct.

Q. And the manual intervention resulted in CMS making a choice in its discretion, correct?

A. Correct.

(Robben Decl., Ex. 23 at 498:16-499:9.)

Plaintiffs' Response: Plaintiffs do not dispute this statement, but incorporate by reference their response to SOF 73.

### C. CMS Reviewed Market Information When It Set FULs

96. Pursuant to federal law, all drug manufacturers whose drugs are reimbursed under state Medicaid programs must enter into a rebate agreement (the “Rebate Agreement”) with the United States Secretary of Health and Human Services, and report Average Manufacturer Prices (“AMPs”) to CMS on a quarterly basis. *See 42 U.S.C. § 1396r-8(a)(1), (b)(3)(A).* The Rebate Agreement sets forth a comprehensive definition of AMP as an average of the discounted unit price of a drug:

(a) “Average Manufacturer Price (AMP)” means, with respect to a Covered Outpatient Drug of the Manufacturer for a calendar quarter, the average unit price paid to the Manufacturer for the drug in the States by wholesalers for drugs distributed to the retail pharmacy class of trade (excluding direct sales to hospitals, health maintenance organizations and to wholesalers where the drug is relabeled under that distributor’s national drug code number). Federal Supply Schedule prices are not included in the calculation of AMP. AMP includes cash discounts allowed and all other price reductions (other than rebates under section 1927 of the Act), which reduce the actual price paid. It is calculated as a weighted average of prices for all the Manufacturer’s package sizes for each Covered Outpatient Drug sold by the Manufacturer during that quarter. Specifically, it is calculated as Net Sales divided by numbers of units sold, excluding free goods (i.e. drugs or any other items given away, but not contingent on any purchase requirements). For Bundled Sales, the allocation of the discount is made proportionately to the dollar value of the units of each drug sold under the bundled arrangement. The Average Manufacturer Price for a quarter must be adjusted by the Manufacturer if cumulative discounts or other arrangements subsequently adjust the prices actually realized.

(Robben Decl., Ex. 50, at § I(a) (Enclosure A).) Each of the capitalized terms incorporated in the AMP definition set forth above is further defined by the Rebate Agreement. (Robben Decl., Ex. 50, at § I.)

Plaintiffs' Response: Plaintiffs do not dispute that the Medicaid Drug Rebate Agreement defines the Average Manufacturer Price as reflected in SOF 96, but dispute the relevance of AMP as California did not sue Defendants based on the accuracy of their reported AMPs.

97. Ms. Gaston testified that she had access to the AMP information that manufacturers reported to CMS. (Robben Decl., Ex. 12 at 528:1-3 (“Q. Would you have had access to that AMP information? A. Yes.”).)

Plaintiffs' Response: Disputed to the extent the statement seeks to establish as fact that CMS could use AMPs for reimbursement purposes, ignores that AMPs were confidential, and ignores that AMPs are not published prices or WACs. Ms. Gaston also testified that CMS did not use AMPs in setting FULs. (Robben Decl. Ex. 12 at 528:1-6.) Moreover, pursuant to the Rebate Agreement, the AMPs provided to CMS are confidential and not to be disclosed by CMS except for the purpose of carrying out the Rebate Program. 42 U.S.C. § 1396r-8(b)(3)(D). This Court has already addressed this issue at length and found AMPs to have been confidential and “not to be revealed to third parties.” *Massachusetts v. Mylan Labs.*, 608 F. Supp. 2d 127, 152 (D. Mass. 2008). In this instance, the third parties would be the state Medicaid programs because only the drug companies and CMS normally are privy to AMP information.

98. CMS officials received feedback from members of the pharmacy community and from State Medicaid agencies about “whether they felt that the FUL prices or the drugs were correctly on the FUL list or needed [to be] adjust[ed]”; whether the product was “available”; and whether “the pricing appears to be either too low or too high.” (Robben Decl., Ex. 12 at 433:14-434:8, 435:8-11; *see also* Robben Decl., Ex. 48 at 110:14-21 (stating that in addition to feedback from industry groups, she received feedback “from pharmacy providers or states”)).

Plaintiffs' Response: Disputed because statement is unclear as to time period and the cited references do not support the statement. CMS witnesses testified that during the 2000 time period, CMS solicited comments from states and pharmacy associations regarding a draft FUL list CMS created without engaging in any manual review process. (*See* Robben Decl. Ex. 12 at 432:14-433:6.) At other times outside of the above-described 2000 time period, when CMS

received feedback from pharmacies, the feedback usually concerned availability of the drug. (*See id.* at 434:19-435:11.) Pharmacies may have also notified CMS that the FUL price was either “too low or too high.” (*Id.* at 435:6-11.) When CMS received feedback that a drug was not available, CMS would call the manufacturer to verify if it was true. (*Id.* at 435:12-21.)

99. In response to feedback that a drug was not available, CMS officials would “call the manufacturer or wholesaler and verify if that was a fact.” (Robben Decl., Ex. 12 at 435:12-21; *see also* Robben Decl., Ex. 48 at 111:12-17 (stating that in response to feedback, Ms. Sexton “would look at the availability in the compendia” or “call suppliers”)).

Plaintiffs’ Response: Undisputed.

100. CMS officials telephoned drug manufacturers, wholesalers, or a compendia publisher when the databases did not provide the WAC for a particular NDC or to determine whether a drug was available. (Robben Decl., Ex. 48 at 60:22-61:7 (“There were times when we would call or I would call the manufacturers or the suppliers to determine if a drug was available. . . . [S]ome of these drugs were looked at, most of them, on a case-by-case basis because there were times when we would have three or more suppliers but perhaps we were missing a wholesale acquisition cost, for instance.”); *id.* at 60:12-16 (“[I]f you just looked at the prices that were on the pricing sheet and there was a wholesale acquisition cost that was missing, that could have had a lower wholesale acquisition cost than the prices that were shown . . . ”); *id.* at 116:1-116:14 (“So to determine whether there was a lower WAC out there, that looks like that was the impetus for the calls.”)).

Plaintiffs’ Response: Undisputed.

101. Ms. Gaston testified that she would sometimes review state MAC prices to “verify that the FUL price that we establish is in the ballpark” and “looks realistic for states.” (Robben Decl., Ex. 12 at 478:17-479:9.)

Plaintiffs’ Response: Plaintiffs do not dispute Ms. Gaston’s testimony about Federal Upper Limit (“FUL”) and Maximum Allowed Cost (“MAC”) prices, which simply operate as a maximum or ceiling price which caps reimbursement. Accordingly, FUL or MAC prices do not exclusively form the basis for Medicaid reimbursement, even when FUL or MAC prices are effective, since the California reimbursement methodology is a lesser of formula.

**PLAINTIFFS' STATEMENT OF ADDITIONAL UNDISPUTED FACTS  
IN OPPOSITION TO DEFENDANTS' MOTIONS FOR  
PARTIAL SUMMARY JUDGMENT**

1. Based upon a methodology more fully set forth in his report, Plaintiffs' expert, Dr. Leitzinger, concludes that total overpayments by the State of California on Medi-Cal reimbursements for Dey identified pharmaceutical products during the period from January 1, 1994 through December 31, 2004 equal \$30.1 million. (Paul Ex. 11 (12/18/09 Leitzinger Decl.), at Ex. A, ¶ 7.) In calculating the overpayments made by the State for the 28 relevant Dey NDCs, Dr. Leitzinger excluded claims for which the actual reimbursement did not exceed the average net price paid by wholesalers to Dey by at least 25 percent. For each remaining claim, he calculated the overpayment as the difference between the actual ingredient cost reimbursed by the State and an amount that is 25 percent above the average net price paid by wholesalers to Dey. (Paul Ex. 12 (11/19/09 Leitzinger Dey Decl.) ¶ 7.)

Based upon a methodology more fully set forth in his report, Plaintiffs' expert, Dr. Leitzinger, concludes that total overpayments by the State of California on Medi-Cal reimbursements for Mylan identified pharmaceutical products during the period from January 1, 1994 through December 31, 2004 equal \$104.4 million. (Paul Ex. 11 (12/18/09 Leitzinger Decl.), at Ex. B, ¶ 7.) In calculating the overpayments made by the State for the 217 relevant Mylan NDCs, Dr. Leitzinger excluded claims for which the actual reimbursement did not exceed the average net price paid by wholesalers to Mylan by at least 25 percent. For each remaining claim, he calculated the overpayment as the difference between the actual ingredient cost reimbursed by the State and an amount that is 25 percent above the average net price paid by wholesalers to Mylan. (Paul Ex. 13 (11/19/09 Leitzinger Mylan Decl.) ¶ 7.)

Based upon a methodology more fully set forth in his report, Plaintiffs' expert, Dr. Leitzinger, concludes that total overpayments by the State of California on Medi-Cal reimbursements for Sandoz identified pharmaceutical products during the period from January 1, 1994 through December 31, 2004 equal \$142.6 million. (Paul Ex. 11 (12/18/09 Leitzinger Decl.), at Ex. C ¶ 7.) In calculating the overpayments made by the State for the 149 relevant Sandoz NDCs, Dr. Leitzinger excluded claims for which the actual reimbursement did not exceed the average net price paid by wholesalers to Sandoz by at least 25 percent. For each remaining claim, he calculated the overpayment as the difference between the actual ingredient cost reimbursed by the State and an amount that is 25 percent above the average net price paid by wholesalers to Sandoz. (Paul Ex. 14 (11/19/09 Leitzinger Sandoz Decl.) ¶ 7.)

2. Former Chief Deputy Director of Health Services, Stanley Rosenstein, testified that the reporting of inflated AWPs by drug manufacturers directly caused Medi-Cal to reimburse pharmacists in excessive amounts, which cost the Program hundreds of millions of taxpayer dollars. (Paul Ex. 4 (11/6/08 Rule 30(b)(6) CA Dept. of Health Care Servs. (Rosenstein) Dep.) at 303:19-304:11; 310:11-311:2.) Mr. Rosenstein testified:

Q. If manufacturers AWPs had been reported by the manufacturers owning those AWPs as actual and accurate measures of their -- of the average wholesale prices of those drugs, would that have affected Medi-Cal's efforts to contain its drug reimbursement costs?

MR. BUEKER: Objection as to form.

THE WITNESS: Yes. We have been spending -- we spent all day talking about the effort we've had to get accurate pricing. Had we started with accurate pricing, we wouldn't have had to go through all of these changes, and we would have had an accurate reimbursement system in the Medi-Cal program. That would have saved the taxpayers hundreds of millions of dollars.

(*Id.* at 303:19-304:11.) Mr. Rosenstein further testified:

Q. Do you believe that the Medi-Cal program has been defrauded by manufacturers who have reported inflated AWPs knowingly to the program?

MR. BUEKER: Objection as to form. Calls for a legal conclusion.

BY MR. PAUL:

Q. Do you believe the program has been cheated?

MR. BUEKER: Objection as to form.

THE WITNESS: Yeah, I believe we have been. I believe the taxpayers have had to pay excessive amounts of money because of incorrectly reported and incorrectly reported AWPs.

(*Id.* at 310:11-311:2.)

3. Demonstrative charts, based on Dr. Leitzinger's calculations, graphically portray the extent of the spreads for four of each Defendant's Subject Drug NDCs. These charts show the gulf between Defendants' reported AWPs versus Dr. Leitzinger's calculated "but-for" average net quarterly prices. (Paul Ex. 15 (Demonstrative Charts).)

4. Plaintiffs' expert Dr. Schondelmeyer concludes that Defendants Dey, Mylan, and Sandoz reported inflated prices to the commercial price databases used by Medi-Cal that were not reasonably or fairly indicative of the "prices generally and currently paid by providers" in the marketplace during the period beginning January 1, 1994 through December 31, 2004. (Paul Ex. 16 (Schondelmeyer Expert Report) ¶ 184.)

5. California Senate Bill 393 was chaptered into law on October 10, 1999. Among other things, Senate Bill 393 required DHCS to "conduct a study of the adequacy of Medi-Cal pharmacy reimbursement rates including the cost of providing prescription drugs and services." The bill was ultimately chaptered as Cal. Bus. & Prof. Code § 4426. (Pls.' Request for Judicial Notice ("RFJN") Ex. 1.)

6. The Myers & Stauffer report compares Mylan's Piroxicam 20mg capsule's AWP of \$2.6391 against its average cost of acquisition of .0339 cents for a spread on ingredient costs of \$2.61—i.e., a spread percentage of 7685%. (Declaration of Suzanne Graydon (“Graydon Decl.) ¶¶ 1-7 & Ex. 1 at line 13.)

7. California Budget Trailer Bill Assembly Bill 442 was voted upon by the California Senate on June 29, 2002, was voted upon by the California Assembly on September 1, 2002, and was approved by the Governor on September 30, 2002. (Pls. RFJN Ex. 2.)

8. The California Legislature did not rely upon the Myers & Stauffer report when considering the proposed change in the Medi-Cal prescription drug reimbursement rate from AWP-5% to AWP-10% pursuant to California Budget Trailer Bill AB 442. This fact is verified by the testimony of the Chief of the Medi-Cal Pharmacy Policy Unit, Dr. Kevin Gorospe. (Paul Ex. 1 (12/3/08 Rule 30(b)(6) CA Dept. of Health Care Servs. (Gorospe) Dep.) at 246:3-16.) Dr. Gorospe testified:

BY MR. HENDERSON:

Q. ... After this report was -- was issued by Myers and Stauffer did the California Legislature enact changes to the reimbursement methodologies by California?

A. There were changes in the methodology in 2002, but the report -- this report was issued too late in the budget cycle process for it to be used in those decisions by the Legislature. They had already moved forward a proposal.

*Id.*

9. The Governor did not have line-item veto authority for California Budget Trailer Bill AB 442. (Paul Ex. 17 (5/19/09 Rosenstein Dep.) at 171:6-171:13, 178:22-179:12.) In this regard, Mr. Rosenstein testified:

Q. Okay. If you could turn to page 10 of the document. Actually, my apologies. Before we go to page 10, just to stay on the first page for a

moment, AB 442 was designed to implement portions of the 2002/2003 State budget; correct?

A. That is correct.

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Q. And in this document the Department is recommending that the Governor not veto Section 73; correct?

A. Well, recommending he not veto the entire bill. With the trailer bill he does not have line item veto, so he either signs the entire bill or vetoes the entire bill.

Q. And that would include Section 73?

A. That's right.

Q. As a result Section 73 became law in California; is that right?

A. That's correct.

*Id.*

10. Section 73 of California Budget Trailer Bill AB 442 provided for the reduction in reimbursement from AWP-5% to AWP-10% in 2002. The trailer bill consists of 106 sections and extends over 150 pages in the California Legislative Digest. (Pls.' RFJN Ex. 3.)

11. As more fully set out in his report, Plaintiffs' expert, Professor Marmor, reports that throughout the relevant time period from 1994 through 2004, California faced significant fiscal challenges and, with respect to Medi-Cal prescription drug reimbursement issues, took extensive steps to comply with its obligation to provide access to Medi-Cal beneficiaries and reduce public expenditures, despite ongoing political and legal attacks against Medi-Cal from other stakeholders. (Paul Ex. 18 (Marmor Report) ¶¶ 88-92.) Specifically, Professor Marmor observes:

In 1994-95, California was in the throes of a state fiscal crisis. Without study, the legislature reduced the reimbursement for each drug claim by 50

cents, a figure later reduced to 25 cents, and then 10 cents. The legislature tried to take other steps at this time, but none other than the claim reimbursement reductions and the supplemental rebate contracts described in the previous paragraph were enacted. The historical record shows that these were efforts to reduce public expenditures, not efforts to reform the drug reimbursement system nor deal with possible fraud.

...

The legislature was in stalemate for much of the period 1996-2002. In 2002, the legislature decided that drug reimbursement would be decreased to AWP-10%, eliminated direct price payments (DP) as a standard, and kept the same dispensing fee. It is my understanding that the defendants claim that this modest decrease in some way supports their claims of approval or acquiescence. I disagree. There were continuing battles, both political and legal, during this period. See, e.g., *Orthopaedic Hospital v. Belshe*, 103 F.3d 1491 (9th Cir. 1997) (describes lengthy litigation over reimbursement rates in California). Efforts to make change that were thwarted by lobbying and litigation—or slowed by independent study—hardly qualify as evidence of approval or acquiescence in the pharmaceutical companies' conduct.

By 2002, the indicators of increasing spreads between reported and acquisition costs prompted the legislature to enact an increased discount from AWP-5% to AWP-10%. Shortly after the 2002 changes were implemented, Myers & Stauffer issued its report. The report distinguished between acquisition costs and dispensing fees. In response, in 2004, the legislature made a more substantial change to AWP -17%. That change was part of an overall adjustment of policy. There was an increase in dispensing fees: from \$4.05 to \$7.25 (for pharmacies) and \$8 (for long term care facilities).

During the relevant time period and at the federal level, the pharmaceutical companies resisted any changes to the AWP method--or alternative measures--through vigorous and costly lobbying. In California, there were other forms of resistance to increases in AWP discounting or alternative methods of reimbursement. In Dey's case, a lawsuit was filed, which sought to enjoin First Data Bank from reporting much lower and apparently more accurate prices. See Complaint in *Dey v. First Data Bank, Inc.*, Superior Court of the State of California (Napa County), Case No. 26-21019 (April 15, 2003)....

*Id.*

12. Medi-Cal relies upon the accuracy of all stakeholders. (Paul Ex. 4 (11/06/08 CA Dept. of Health Care Servs. (Rosenstein) Dep.) at 301:15-302:6.) In this regard, Mr. Rosenstein testified as follows:

Q. And to your knowledge, is it the intent of the Medi-Cal program that manufacturers report AWPs as an accurate measure of average wholesale prices?

MR. BUEKER: Objection. Form.

THE WITNESS: Absolutely. We depend upon the accuracy and the integrity of everybody who participates in the program. It is a humongous revised program with a relatively small staff. In all aspects of it, it depends upon the people who provide the government, the state, the federal government with data they do accurately.

*Id.*

13. The failure of manufacturers to report accurate pricing resulted in Medi-Cal having to make changes to its reimbursement policies and has resulted in an inaccurate reimbursement system. (Paul Ex. 4 (11/06/08 CA Dept. of Health Care Servs. (Rosenstein) Dep.) at 303:19-304:11.) In this regard, Mr. Rosenstein testified as follows:

Q. If manufacturers AWPs had been reported by the manufacturers owning those AWPs as actual and accurate measures of their -- of the average wholesale prices of those drugs, would that have affected Medi-Cal's efforts to contain its drug reimbursement costs?

MR. BUEKER: Objection as to form.

THE WITNESS: Yes. We have been spending -- we spent all day talking about the effort we've had to get accurate pricing. Had we started with accurate pricing, we wouldn't have had to go through all of these changes, and we would have had an accurate reimbursement system in the Medi-Cal program. That would have saved the taxpayers hundreds of millions of dollars.

*Id.*

14. But-for the failure of drug manufacturers to report accurate prices, Medi-Cal could have saved hundreds of hours in Program resources, which could have been better used to improve the Program. (Paul Ex. 4 (11/06/08 CA Dept. of Health Care Servs. (Rosenstein) Dep.) at 311:4-312:4.) In this regard, Mr. Rosenstein testified as follows:

Q. Earlier in your testimony in response to questions from counsel for Warrick, I think you mentioned at one point that Dr. [Gorospe] conducted some interviews or participated in interviews with the participating pharmacies sometimes around 2004. And I think you used the phrase, "This was a resource intensive effort on the part of Dr. [Gorospe] and his pharmacists"; is that correct?

A. That's correct.

Q. And would you agree that had the generic drug manufacturers accurately reported their AWPs as actual average wholesale prices that that resource intensive effort would not have had to take place?

MR. BUEKER: Objection as to form.

THE WITNESS: We would have saved hundreds of hours of our pharmacist's time that both that effort which took weeks and throughout this whole process, time that he could have better been spent on other ways to improve the Medi-Cal program.

*Id.*

15. It has never been the policy of the Medi-Cal program to deliberately accept inflated and inaccurate AWPs simply because the program knew it would offset them by shorting or minimizing the amount of the filling fee for pharmacists, or because it might be able to offset the effect of inflated AWPs with rebates. (Paul Ex., Paul Ex. 4 (11/06/08 CA Dept. of Health Care Servs. (Rosenstein) Dep.) at 313:10-314:3].) In this regard, Mr. Rosenstein testified as follows:

Q. Just to be clear, I want to confirm with you whether or not, has it ever been the policy of the Medi-Cal program to deliberately accept inflated and inaccurate AWPs simply because the program knew it would offset

them by shorting or minimizing the amount of the filling fee for pharmacists?

MR. BUEKER: Objection as to form.

MR. CYR: Objection.

THE WITNESS: No. It has always been our policy to have accurate information and to use that information to establish what the accurate price should be, should be on both ends of the equation. We do believe they need to be both looked at, but they have got to come from accurate data sources.

*Id.*

16. There is no evidence that the California Legislature ratified Defendants' reporting of grossly inflated AWPs. (Paul Ex. 4 (11/06/08 CA Dept. of Health Care Servs. (Rosenstein) Dep.) at 308:12-309:1.) In this regard, Mr. Rosenstein testified that he never heard any legislator or staffer indicate an acceptance of inflated or untruthful AWPs, but rather that he had heard strong objections to the government receiving false information.

Q. Did you ever hear of any staffer or legislator in either the Senate or the Assembly state an acceptance of inflated AWPs or acceptance of reimbursement from the Medi-Cal program of pharmacy drugs based on inflated or untruthful AWPs?

MR. BUEKER: Objection as to form.

MR. CYR: Objection.

THE WITNESS: No, I do not. In fact, I have heard it quite the opposite of strong objection to the government getting false information.

*Id.*

17. Defendant Sandoz' expert David Rubinfeld admits that Sandoz AWPs could not be used to estimate acquisition cost without independent information about prices actually paid by providers. (Paul Ex. 19 (9/29/09 Rubinfeld Dep.) at 135:2-135:14.) In this regard, Dr. Rubinfeld testified as follows:

Q. Would it be accurate to say that you would need some actual or average price information about selling prices of Sandoz's drugs in order to come up with an appropriate discount off of AWPs to end up with an estimate of the price generally and currently paid?

A. I would say it slightly differently. I would say that you would need independent information as to Sandoz invoice prices. You couldn't—you wouldn't know what discount, if any, to have off AWP as a benchmark unless you actually had information about prices actually paid.

*Id.*

18. In 1989, California revised Section 51513 of Title 22 of the California Code of Regulations ("CCR") to establish the basic formula that governed Medi-Cal's pharmaceutical reimbursement methodology through November 30, 2002. (Robben Decl. Ex. 13, Pl.'s Resp. to Defs. Interrog # 13.)

19. The Regulation was revised through a formal rulemaking proceeding. The Final Statement of Reasons for the revision states that "the State must come as close as possible to the actual acquisition cost. The AWP-5% program is the State's best estimate of this cost." (Paul Decl. Ex. 20 at 2.)

The Addendum to the Final Statement of Reasons issued by DHS in connection with the revisions to the Regulation made clear that California's policy was to *not* cross-subsidize allegedly inadequate dispensing fees by allowing excess ingredient cost payments, stating as follows: "[C]urrent federal regulations at 42 C.F.R. 447.332, require the Department to make drug reimbursements based on the estimated acquisition cost of the drug without including any loss on dispensing fee requirements." (Paul Decl. Ex. 20 at 1.) That document also made clear that California's reimbursement formula was calculated to estimate providers' acquisition costs as accurately as possible, stating: "An analysis of existing elements of Medi-Cal reimbursement, such as the FAC, MAIC and direct price, determined that when combined with AWP-5%, they

resulted in an overall discount which was equal to the Department's best estimate of the price generally and currently paid by pharmacy providers." (*Id.* at 2-3.)

20. The 2002 Myers & Stauffer study found, *inter alia*, as follows:

For some multi-source drug products without federal upper limits, the acquisition cost as a percentage of the AWP is similar to those of single source drugs. However, there are a significant number of products purchased with acquisition costs much lower than the 80% to 85% range observed for single source drugs.

(Robben Decl. Ex. 34 at 22.) There was significant variation in the discount from AWP at which such products could be purchased. (*Id.*) The report also found that "[f]or calendar year 200, approximately \$182 million in savings was obtained by reimbursing the FUL price instead of the EAC price." (*Id.* at 23.)

21. The 2002 Myers & Stauffer study recommended, *inter alia*, as follows:

In light of these findings, we recommend that the Department should consider increasing the discount from the Average Wholesale Price (AWP) for both single source and multi-source drugs. The acquisition cost study indicates that the Department could justify setting ingredient reimbursement for brand name drugs at a level between AWP minus 12% and AWP minus 15%. The study would also support a differential reimbursement rate for generic drugs such as one between AWP minus 20% and AWP minus 25%.

\* \* \*

FUL and MAC systems are appropriate for certain multi-source drugs where the relationship of acquisition cost to the AWP can be highly skewed (e.g., acquisition cost of AWP minus 90% or greater is not uncommon) and incentives to promote generic utilization are appropriate.... An expansion of MAIC pricing to cover a more comprehensive set of multi-source drugs might be desirable.

(Robben Decl. Ex. 33 at 5-6.)

22. A March 11, 2003 report issued by the California Assembly Committee on Health, titled "Prescription Drugs: Why Are They So Expensive? What Can We Do to Control Costs?" states, in part, as follows:

. . . the "true" cost of prescription drugs has grown increasingly elusive. According to a National Health Policy Forum Issue Brief published in 2002, drug prices are subject to various types of discounts and rebates, seen and unseen on both the public and private side. Each drug sold by a manufacturer is subject to multiple prices, and little is known publicly about this pricing information.

Table 1 lists ten commonly used pricing methodologies and the relative cost of an "average" prescription drug under each methodology. For any individual drug, only three of the ten prices are published, and only the Average Wholesale Price (AWP) is widely available and includes all drugs.

(Paul Decl. Ex. 21 (11/6/08 Rule 30(b)(6) CA Dept. of Health Care Servs. (Rosenstein) Dep.), Ex. 37 at 3.)

23. The DHS Fact Sheet relating to the 2004 statute states, in pertinent part, as follows:

The 2000 *Study of Med-Cal Pharmacy Reimbursement* [the Myers and Stauffer Report], an independent study mandated by the Legislature, found the average ingredient cost for brand name drugs was Average Wholesale Price (AWP) – 17.2%, and the average ingredient cost for generic drugs was AWP – 43.4%.

The only products for which Medi-Cal knows the actual prices pharmacies pay are blood factors, . . .

\* \* \*

The May [budget] Revision proposed to reimburse pharmacies for both brand name and generic drugs at AWP-20% based on information available at the time.

Review of new data indicates that many of the critical drugs for AIDS and mental health are purchased by pharmacies at about AWP-17%. To continue with average AWP-20% reduction, could affect access to these drugs and would disproportionately affect pharmacies who specialize in

these drugs. Further, they would have a major negative impact on long term care pharmacies.

Based on this new information, the proposal now is to reimburse pharmacies for both brand and generic drugs at AWP-17%.

*At AWP -17% Medi-Cal will still be overpaying the cost of generic drugs, which pharmacies can purchase at AWP-40% or less. Medi-Cal will be implementing maximum allowable ingredient costs to reduce the costs of these drugs.*

(Robben Decl. Ex. 36 (emphasis added).)

24. In 2004, in addition to other changes to the reimbursement rates, the Legislature revised Medi-Cal's MAIC system, providing that "the department shall base the MAIC on the mean of the wholesale selling prices of drugs generically equivalent to the particular innovator drug that are available in California from wholesale drug distributors selected by the department." CAL. WELF. & INST. CODE § 14105.45(b)(3)(A).

25. Due to a lack of cooperation from the industry, DHS was not able to effectuate the above change in the MAIC program. (Paul Decl. Ex. 4 (11/6/08 Rule 30(b)(6) CA Dept. of Health Care Servs. (Rosenstein) Dep.) at 296:14-299:14.)

26. CMS received AMP information from drug manufacturers for the sole purpose of use in the Medicaid Drug Rebate Program. AMPs were not used by CMS to set FULs because AMPs were confidential and were not published in the national compendia. (Paul Decl. Ex. 9 (Declaration of Susan E. Gaston, June 15, 2009), at ¶ 6.)

27. Ms. Gaston testified that her general practice was to use WACs that were published in one or more of the national compendia to set the FULs. (Paul Decl. Ex. 9 (Declaration of Susan E. Gaston, June 15, 2009), at ¶ 3.)

28. Ms. Gaston testified that had drug manufacturers supplied lower WACs to the publishing compendia, she would have considered those WACs in the context of setting FULs

provided those lower WACs were not outliers. (Paul Decl. Ex. 9 (Declaration of Susan E. Gaston, June 15, 2009), at ¶ 7.)

29. The former Chief Deputy Director of Health Care Services, Stanley Rosenstein, testified as follows:

BY MR. PAUL:

Q. With regard to generic manufacturers, has any generic manufacturer, to your knowledge, ever come to the Medi-Cal program and provided information to explain to the program the difference between actual provider costs and its reported AWPs for any of its drugs?

A. Not in the 13 years that I have been a part of running the Medi-Cal program.

Q. So that statement would apply to the four defendants who are represented by counsel at this table?

A. That's right. No one has come to my office and told us that. And we have other providers who have come to us and disclosed, you know, inaccurate claiming over the past. It does happen, but none of the drug manufacturers have come to me and made that disclosure.

Mr. Rosenstein further testified as follows:

Q. I think you were showed earlier in the day an exhibit. I think it was Exhibit 5, a 1996 report by the OIG concerning its examination of the discrepancy between AWPs and acquisition costs for generic and branded drugs. Do you recall that?

A. Yes.

Q. To your knowledge, did any manufacturer come to the Medi-Cal program after the OIG issued that report to offer help in reforming its reporting of AWPs?

A. No.

Q. Did any manufacturer come to the program expressing any concern about the implications of that report to your knowledge?

A. Not to my knowledge, and never to me.

(Paul Decl. Ex. 4 (11/6/08 Rule 30(b)(6) CA Dept. of Health Care Servs. (Rosenstein) Dep.) at 302:8-303:18.)

30. Under Medi-Cal's system of reimbursement, drug manufacturers reported AWPs are used as one of the reference prices within California's Estimated Acquisition Cost reimbursement methodology, which pays the "lowest of" (for the purposes of California's lawsuit), AWP, FUL, or Usual and Customary ("U&C") as the ingredient cost. In some cases, the reported AWPs for some Subject Drugs, once discounted by the statutorily required minus-5%, 10% or 17% (depending on the year), would result in an ingredient cost that was lower than the FUL limit for the generic drug product. (Paul Decl. Ex. 16 (Schondelmeyer Expert Report) ¶¶ 19, 139; Paul Decl. Ex. 22 (9/15/09 Schondelmeyer Dep.) at 206:10-22; Paul Decl. Ex. 23 (9/16/09 Schondelmeyer Dep.), 474:5-15, 613:1-614:11, 659:18-660:6.)

31. Plaintiffs retained Dr. Jeffrey Leitzinger to perform analyses and calculations from the Medi-Cal data associated with provider claims which were paid by Medi-Cal during the relevant time period, and concern Defendants' drugs at issue in California's case. Dr. Leitzinger's report identifies approximately 28.7 million such claims (approximately 1.0 million for Dey, 14.9 million for Mylan and 12.8 million for Sandoz). Within that universe of claims, Dr. Leitzinger has verified (following the same claim payment identification method employed by Defendant Sandoz's data analysis expert), approximately 312,000 reimbursed claim payments for which the reimbursement price per unit (i.e., the price which defined the reimbursement amount for each such Medi-Cal claim) was *less* than the published FUL, *and* based on AWP-based reimbursement (i.e., AWP minus the California statutory discount of minus 5, 10 or 17% [the amount of the discount depends on the year in which the claim was paid]). As reflected in the same claims data, there are approximately 62,000 additional claims that were reimbursed at

an amount that was *less* than the published FUL, *and* was based on the pharmacy's reported Usual and Customary ("U&C") charge. *In other words, the claims data in the record contains approximately 374,000 claims which were paid (a) at a figure which was less than the FUL, and (b) was based on either "AWP-minus the statutory discount", or U&C.* (Paul Ex. 11 (12/18/09 Leitzinger Decl.) ¶¶ 1-6.)

32. The Myers & Stauffer reports cost between \$400,000 and \$500,000 dollars, paid for by California and federal government monies. (Paul Decl. Ex. 4 (11/6/08 Rule 30(b)(6) CA Dept. of Health Care Servs. (Rosenstein) Dep.) at 312:20-313:9.)

33. The CMS FULs analyst has limited ability to affect the output of the FULs system. A system upgrade in 1999 provides the only such limited ability. The 1999 upgrade allows the FULs analyst to annotate the FULs System data by assigning a "T" or "P" exclusion code to an NDC to indicate that the product is temporarily or permanently unavailable (typically based on the analyst's communications with the manufacturer). Products with such designations still appear in the FULs data systems, but are not considered when the FUL is set. Second, the FULs analyst has the ability to re-designate an NDC to a Product Group in the event the analyst learns of an error in the FULs system matching process. With these two limited exceptions, the FULs analyst does not exercise discretion to include or exclude products from the list that appears in the FULs data system array of prices from which the FUL is determined. (Paul Decl. Ex. 10 (Coffman Decl.) ¶ 17.)

Dated: December 21, 2009

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of the Case Management Order No. 2, by sending on December 21, 2009, a copy to Lexis-Nexis for posting and notification to all parties.

/s/ Nicholas N. Paul  
NICHOLAS N. PAUL